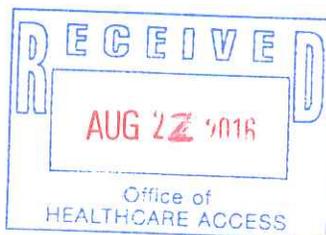




Connecticut Orthopaedic Specialists, P.C.

THE EXPERIENCE MATTERS



August 19, 2016

Ms. Kimberly Martone
Director of Operations
State of Connecticut Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Connecticut Orthopaedic Specialists, P.C.
Acquisition of a 1.5 Tesla MRI Mobile Unit

Dear Ms. Martone,

Attached please find one (1) hard copy in a 3-ring binder and a USB flash drive of Connecticut Orthopaedic Specialists' Main Certificate of Need Application and the Supplemental Application for the acquisition of a 1.5 Tesla Mobile MRI unit. Also attached is a disc containing both application forms in Adobe format.

Please feel free to contact me if you have any questions with regard to this application.

Very truly yours,



Glenn F. Elia, CEO
Connecticut Orthopaedic Specialists, P.C.

2408 Whitney Avenue, Hamden, Connecticut 06518

Billing 203.407.3560 • Main 203.407.3500 • Fax 203.281.1164 • ct-ortho.com

**State of Connecticut
Department of Public Health
Office of Health Care Access**

**Certificate of Need Application
Main Form**
Required for all CON applications

Contents:

- Checklist
- List of Supplemental Forms
- General Information
- Affidavit
- Abbreviated Executive Summary
- Project Description
- Public Need and Access to Health Care
- Financial Information
- Utilization

Checklist

Instructions:

1. Please check each box below, as appropriate; and
 2. The completed checklist *must* be submitted as the first page of the CON application.
- Attached is a paginated hard copy of the CON application including a completed affidavit, signed and notarized by the appropriate individuals.
 - (*New*). A completed supplemental application specific to the proposal type, available on [OHCA's website under "OHCA Forms."](#) A list of supplemental forms can be found on page 2.
 - Attached is the CON application filing fee in the form of a certified, cashier or business check made out to the "Treasurer State of Connecticut" in the amount of \$500.
 - Attached is evidence demonstrating that public notice has been published in a suitable newspaper that relates to the location of the proposal, 3 days in a row, at least 20 days prior to the submission of the CON application to OHCA. (*OHCA requests that the Applicant fax a courtesy copy to OHCA (860) 418-7053, at the time of the publication*)
 - Attached is a completed Financial Attachment
 - Submission includes one (1) original hardcopy in a 3-ring binder and a USB flash drive containing:
 1. A scanned copy of each submission in its entirety, including all attachments in Adobe (.pdf) format.
 2. An electronic copy of the applicant's responses in MS Word (the applications) and MS Excel (the financial attachment).

For OHCA Use Only:

Docket No.: 16-32117-CON Check No.: 28893
OHCA Verified by:  Date: ~~8/18~~ 8/21/16

000001

General Information

Name of Applicant:

Name of Co-Applicant:

Connecticut Orthopaedic Specialists, P.C.	N/A
---	-----

Connecticut Statute Reference:

C.G.S. Sec. 19a-638

Main Site	MAIN SITE	MEDICAID PROVIDER ID	TYPE OF FACILITY	MAIN SITE NAME
	Hamden	#004001020 is the MD group #. Physician # is added also.	Private Physician Practice	Connecticut Orthopaedic Specialists, P.C.
	STREET & NUMBER			
	2408 Whitney Avenue			
	TOWN		ZIP CODE	
	Hamden		06518	

Project Site	PROJECT SITE	MEDICAID PROVIDER ID	TYPE OF FACILITY	PROJECT SITE NAME
	Orange			Connecticut Orthopaedic Specialists, P.C.
	STREET & NUMBER			
	330 Boston Post Road			
	TOWN		ZIP CODE	
	Orange		06477	

Project Site	PROJECT SITE	MEDICAID PROVIDER ID	TYPE OF FACILITY	PROJECT SITE NAME
	Essex			Connecticut Orthopaedic Specialists, P.C.
	STREET & NUMBER			
	12 Bokum Road			
	TOWN		ZIP CODE	
	Essex		06426	

Operator	OPERATING CERTIFICATE NUMBER	TYPE OF FACILITY	LEGAL ENTITY THAT WILL OPERATE OF THE FACILITY (or proposed operator)
	N/A	Private Physician Practice	Connecticut Orthopaedic Specialists, P.C.
	STREET & NUMBER		
	2408 Whitney Avenue		
	TOWN		ZIP CODE

Hamden	06518
--------	-------

Chief Executive	NAME		TITLE		
	Glenn F. Elia		CEO		
	STREET & NUMBER				
	2408 Whitney Avenue				
	TOWN		STATE	ZIP CODE	
	Hamden		CT	06518	
	TELEPHONE	FAX	E-MAIL ADDRESS		
	203 407-3576	203 415-8774	gelia@ct-ortho.com		

Title of Attachment:

Is the applicant an existing facility? If yes, attach a copy of the resolution of partners, corporate directors, or LLC managers, as the case may be, authorizing the project.	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	
Does the Applicant have non-profit status? If yes, attach documentation.	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	
Identify the Applicant's ownership type.	PC <input checked="" type="checkbox"/>	LLC <input type="checkbox"/>	Other: _____
Corporation <input type="checkbox"/>			
Applicant's Fiscal Year (mm/dd)	Start January 1 End December 31		

Contact:

Identify a single person that will act as the contact between OHCA and the Applicant.

Contact Information	NAME		TITLE		
	Glenn F. Elia		CEO		
	STREET & NUMBER				
	2408 Whitney Avenue, Hamden, CT 06518				
	TOWN		STATE	ZIP CODE	
	Hamden		CT	06518	
	TELEPHONE	FAX	E-MAIL ADDRESS		
	203 407-3576	203 415-8774	gelia@ct-ortho.com		
RELATIONSHIP TO APPLICANT	CEO				

Identify the person primarily responsible for preparation of the application (optional):

Prepared by	NAME Patricia A. Gerner		TITLE Principal
	The Law Office of Patricia A. Gerner, LLC		
	STREET & NUMBER		
	240 Ramstein Road, P.O. Box 209		
	TOWN	STATE	ZIP CODE
	New Hartford	CT	06057
	TELEPHONE	FAX	E-MAIL ADDRESS
	860 794-1907	860 489-9380	
	RELATIONSHIP TO APPLICANT	Consultant	

000004

CONNECTICUT POST

410 State Street • Bridgeport, CT 06604

CONNECTICUT ORTHOPAEDIC SPECIALISTS,
PC, KELLY
2408 Whitney Avenue
HAMDEN CT 06518

CONNECTICUT POST CERTIFICATE OF PUBLICATION

This is to certify that the
attached advertisement was published
in the Connecticut Post newspaper as
stated below.



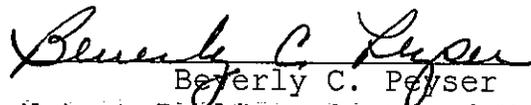
(Advertising Representative)

RECEIVED

JUL 11 2016

COS HAMDEN

Subscribed and sworn to before me,
on this 7.th day of July, A.D. 2016



Beverly C. Peysen
Notary Public - State of New York
No. 01PE6320015

Qualified in Rensselaer County
My Commission Expires
March 2, 2019

PO Number

Amount
\$326.60

Publication
Connecticut Post

Ad Number
0002180047-01

Publication Schedule
7/7/2016, 7/8/2016, 7/9/2016

Ad Caption
Legal Notice Connecticut Orthop

000005

Legal Notice
Connecticut Orthopaedic Special -
ists, P.C. ("COS") is applying to
the CT DPH Office of Health Care
Access for a Certificate of Need
pursuant to Section 19a-638 of
the CT General Statutes in order
to purchase a mobile 1.5 Tesla
MRI to be used two days a week
for orthopedic MRI scanning for
its patients at its office in Orange
and 2 days a week at its office in
Essex. The location in Orange is
330 Boston Post Road. The loca -
tion in Essex is 12 Bokum Road.
The total capital expenditure is
\$ 675,000.00

Hartford Courant

●●●●● media group

AFFIDAVIT OF PUBLICATION

State of Connecticut

June 29, 2016

County of Hartford

I, Janet Tarasuk, do solemnly swear that I am a Sales Assistant of the Hartford Courant, printed and published daily, in the state of Connecticut and that from my own personal knowledge and reference to the files of said publication the advertisement of Public Notices was inserted in the regular edition.

On Dates as Follows:

06/27/2016 72.97; 06/27/2016 10.00; 06/28/2016 72.97;
06/29/2016 72.97

In the Amount of:

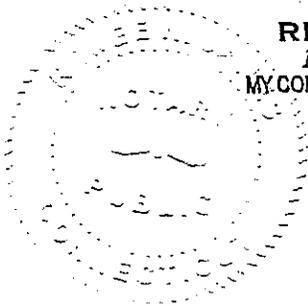
\$228.91
CT Orthopaedic Specialists Inc (HTF) - CU00246101
4281810
Full Run

Janet Tarasuk Sales Assistant,
Janet Tarasuk

Subscribed and sworn before me on June 29, 2016

Renee Janes Notary Public

RENEE N. JANES
NOTARY PUBLIC
MY COMMISSION EXPIRES MAR. 31, 2018



RECEIVED

JUL 05 2016

COS HAMDEN

Order # - 4281810

000007

Hartford Courant

media group

Legal Notice

Connecticut Orthopaedic Specialists, PC ("COS") is applying to the CT DPH Office of Health Care Access for a Certificate of Need pursuant to Section 19a-638 of the CT General Statutes in order to purchase a mobile 1.5 Tesla MRI to be used two days a week for orthopedic MRI scanning for its patients at its office in Orange and 2 days a week at its office in Essex. The location in Orange is 330 Boston Post Road. The location in Essex is 12 Bokum Road. The total capital expenditure is \$ 875,000.00.

Order # - 4281810

000008

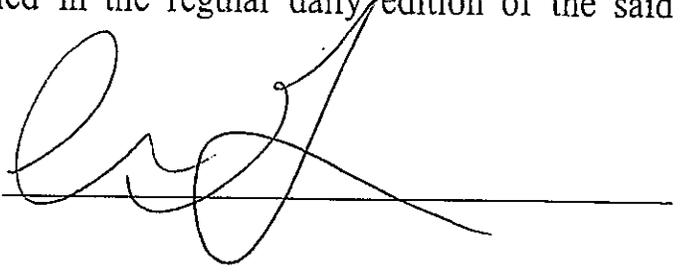
AFFIDAVIT OF PUBLICATION

1050804

NEW HAVEN REGISTER

STATE OF CONNECTICUT, County of New Haven

I Christopher Gilson of New Haven, Connecticut, being duly sworn, do depose and say that I am a Sales Representative of the New Haven Register, and that on the following date 6/27, 28, 29/16..... there was published in the regular daily edition of the said newspaper an advertisement,



Legal Notice
Connecticut Orthopaedic Specialists, P.C. ("COS") is applying to the CT DPH Office of Health Care Access for a Certificate of Need pursuant to Section 19a-638 of the CT General Statutes in order to purchase a mobile 1.5 Tesla MRI to be used two days a week for orthopedic MRI scanning for its patients at its office in Orange and 2 days a week at its office in Essex. The location in Orange is 330 Boston Post Road. The location in Essex is 12 Bokum Road. The total capital expenditure is \$675,000.00

RECEIVED
JUL 25 2016
COS HAMDEN

And that the newspaper extracts hereto annexed were clipped from each of the above-named issues of said newspaper. Subscribed and sworn to this 15th..... day of July 2016.... Before me.



My commission expires July 31, 2019

000010

Connecticut Orthopaedic Specialists, PC
2408 Whitney Avenue
Hamden, CT 06518

First Niagara
50-7044/2223

28893

DATE: 7/19/2016

PAY **500.00**
ONLY Five Zero Zero CENTS

\$ 500.00

PAY Five Hundred and 00/100 Dollars

TO THE ORDER OF Treasurer, State of Connecticut
Division of Health Systems Regulations
PO Box 1080
Hartford, CT 06143-1080

M. D. Bar
AUTHORIZED SIGNATURE

Security features included. Details on back.

Connecticut Orthopaedic Specialists, PC

NAME: Treasurer, State of Connecticut

CHECK DATE: 7/19/2016

28893

500.00

New-FNB Operating 0

500.00

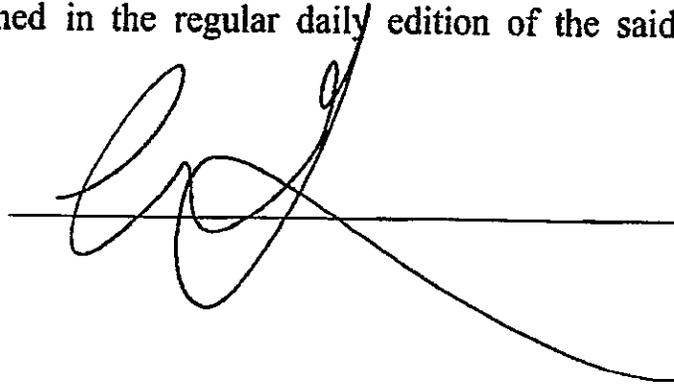
000012

AFFIDAVIT OF PUBLICATION

MIDDLETOWN PRESS

STATE OF CONNECTICUT, County of Middlesex

I Christopher Gilson of New Haven, Connecticut, being duly sworn, do depose and say that I am a Sales Representative of the Middletown Press, and that on the following date .6/27, 28, 29/16..... there was published in the regular daily edition of the said newspaper an advertisement,



Legal Notice

Connecticut Orthopaedic Specialists, P.C. ("COS") is applying to the CT DPH Office of Health Care Access for a Certificate of Need pursuant to Section 19a-638 of the CT General Statutes in order to purchase a mobile 1.5 Tesla MRI to be used two days a week for orthopedic MRI scanning for its patients at its office in Orange and 2 days a week at its office in Essex. The location in Orange is 330 Boston Post Road. The location in Essex is 12 Bokum Road. The total capital expenditure is \$675,000.00

And that the newspaper extracts hereto annexed were clipped from each of the above-named issues of said newspaper. Subscribed and sworn to this 27th day of July, 2016..... Before me.



My commission expires July 31, 2019

Affidavit

Applicant: Connecticut Orthopaedic Specialists, P.C.

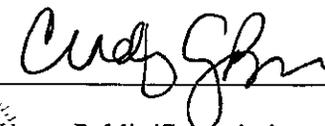
Project Title: Acquisition of a 1.5 tesla Mobile MRI by Private Physician Practice

I, Glenn F. Elia, CEO
(Name) (Position – CEO or CFO)

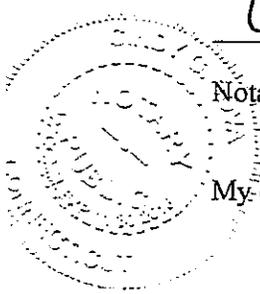
of Connecticut Orthopaedic Specialists, P.C. being duly sworn, depose and state that the (Facility Name) said facility complies with the appropriate and applicable criteria as set forth in the Sections 19a-630, 19a-637, 19a-638, 19a-639, 19a-486 and/or 4-181 of the Connecticut General Statutes.

 7-19-16.
Signature Date

Subscribed and sworn to before me on Nov. 30, 2016


Notary Public/Commissioner of Superior Court

My commission expires: Nov. 30, 2016


CINDY G. BOVA
NOTARY PUBLIC
MY COMMISSION EXPIRES
NOV. 30, 2016

Executive Summary

The purpose of the Executive Summary is to give the reviewer a conceptual understanding of the proposal. In the space below, provide a succinct overview of your proposal (this may be done in bullet format). Summarize the key elements of the proposed project. Details should be provided in the appropriate sections of the application that follow.

This Certificate of Need application ("CON") is being filed by Connecticut Orthopaedic Specialists, P.C. ("COS") in order to purchase a 1.5 Tesla mobile MRI. COS is a single specialty orthopedic physician group practice that has operated in Connecticut as a Professional Corporation for over 50 years. COS currently owns two 1.5 T MRIs, one located in its physician office in Hamden and the other on its outpatient surgery campus in Branford. Both have reached maximum capacity. Both MRIs are being utilized over 12 hours each weekday and on the weekends.

COS recently added other orthopedic physician groups to its group practice. Between 2014 and 2015, COS merged with four other orthopedic physician group practices expanding the total number of physicians' offices to from eight (8) to twenty one (21) with a new total of 49 orthopedic doctors. The new COS physicians have patients in need of orthopedic MRI scanning, and as a result, the volume of MRI scanning has increased rapidly. Also, Hamden and Branford have used up any excess capacity they had prior to 2014.

If approved, the MRI will be mobile, and will operate between two existing COS offices – Orange and Essex. At the outset, the mobile will operate 2 days a week in Orange, two days a week in Essex and will travel between the two locations one day.

MRI service is an important component of treatment for orthopedic patients who require this type of scanning. With a COS radiologist to read the images, reports are ordinarily back to the orthopedic physician overnight if not the same day. Keeping all components of the patient's care within COS results in faster treatment, which keeps the patient's condition from worsening, causing more expensive consequences. COS works with numerous health care insurers in CT to bundle payments, and the MRI fee is included in the bundled cost. There is no facility fee involved.

COS provides MRI services exclusively for orthopedic patients who are being treated by COS physicians. COS does not accept referrals for MRI services from any other source outside of the practice.

Pursuant to Section 19a-639 of the Connecticut General Statutes, the Office of Health Care Access is required to consider specific criteria and principles when reviewing a Certificate of Need application. Text marked with a “§” indicates it is actual text from the statute and may be helpful when responding to prompts.

Project Description

1. Provide a detailed narrative describing the proposal. Explain how the Applicant(s) determined the necessity for the proposal and discuss the benefits for each Applicant separately (if multiple Applicants). Include all key elements, including the parties involved, what the proposal will entail, the equipment/service location(s), the geographic area the proposal will serve, the implementation timeline and why the proposal is needed in the community.

Response:

Description of the Proposal

This CON application is a request from Connecticut Orthopaedic Specialists, P.C. (“COS”) to purchase a mobile 1.5 Tesla MRI to be used at two physician offices for COS patients only. The MRI would be used initially two days a week in Orange and two days a week in Essex, with one day of travel mid-week.

COS is a private physician practice treating only orthopedic patients. It has been in existence for over fifty years, treating patients in south-central Connecticut. With highly trained orthopedic surgeons and health care professionals, COS provides extraordinary care for children and adults with musculo-skeletal injuries and diseases. COS physicians are the Team Physicians for 16 Connecticut high schools, the Quinnipiac University Bobcats and Sacred Heart University.

COS currently has two 1.5 Tesla MRI scanners; one in its Hamden office and the other in its outpatient surgery campus in Branford. Prior to 2014, COS had physician offices in Hamden, Branford, Orange, Guilford, New Haven, Milford, Shelton and Wallingford. Patients who were receiving treatment in Hamden and Branford could have any necessary MRI scanning done in those offices. Other COS patients who lived in close proximity to either Hamden or Branford but were being treated in other COS facilities where there is no MRI, could also use the COS Branford or Hamden locations for MRI scanning.

It has always been the practice of COS to do MRI scanning in-house whenever possible because of time and quality, which leads to a better outcome for the patient. COS has an agreement with Dr. Joseph Gagliardi to professionally read and provide appropriate information and reports for MRI images for COS. Dr. Gagliardi is a COS employee who has a fixed salary.

000015

Offering MRI services within COS has a number of benefits for the patient. The COS orthopedic physician can order the MRI, and book the appointment immediately. The COS radiologist will read and return the report to the orthopedic physician within 24 hours, and often during the same day. This allows the orthopedic physician to begin treatment much faster than if the patient has to go elsewhere to book an MRI, wait for the results and wait for the radiologist to contact the orthopedic doctor to transmit those results.

MRI scanning is built in to the cost for orthopedic care at COS if the patient's insurer accepts this payment method. COS has begun using a "bundled payment" system where there is one bill to treat a patient for the particular orthopedic diagnosis, and this one cost includes everything from the first visit to the completion of treatment. It is a value based system, focusing on best practices. Individual costs for each part of the treatment are not billed individually, which makes the overall cost more economical. In addition to the saving of time and the connection between all parts of the patient's care with in-office scanning, COS has negotiated with a couple of its largest payers to lower prices by bundling the fees. These savings are passed on to the patients, and help to lower health care costs in Connecticut.

Need for the Proposal

Until the last two years, COS had enough scanning capacity to treat the COS patients in its Hamden and Branford offices. However, during a two year period between 2014 and 2015, the COS practice grew with the addition of four private practice orthopedic physician groups. This has more than doubled the number of COS offices, and greatly expanded the volume of patients. None of these groups own or lease an MRI, and COS is using its two existing MRIs for a practice that now has 49 physicians and 21 locations (an expansion from 8 to 21 physician offices). See Exhibit A for a map of the current COS offices, a listing of all 21 office locations and a listing of all of the physicians practicing in each of the new COS offices prefaced by a list of the COS physicians prior to the mergers. The two existing COS fixed MRIs located in the Hamden office and on the Branford outpatient surgery campus, have reached maximum capacity, even with expanded hours.

The four orthopedic physician practices that merged with COS are:

- Center for Orthopedics: General and Specialty Care, with physician offices located in Orange, New Haven, Norwalk, Hamden and Branford;
- Shoreline Orthopedics & Sports Medicine with physician offices in Essex, Madison and Guilford;
- The Orthopedic Group with physician offices in Milford, Branford, Hamden and Wallingford; and
- Orthopedic Health with one physician office in Milford.

All of these offices are single-specialty practices where a physician covers the patient care from the beginning of the orthopedic health issue to its conclusion.

As the two COS MRI units experienced greater demand after 2014, both locations began offering expanded office hours. Currently, both COS offices with an MRI unit are open 13 hours on weekdays and 10 hours on Saturdays.¹ In addition, the Hamden office regularly sees patients on Sunday as necessary. The hours have expanded from 64 hours per week to 75 hours per week plus the availability of MRI scanning on Sunday. The current hours for each of the two existing locations are:

Hamden

Monday – Friday: 7:00 A.M. – 8:00 P.M.

Saturday: 7:00 A.M. – 5:00 P.M.

Sunday: By appointment

Branford

Monday – Friday: 7:00 A.M. – 8:00 P.M.

Saturday: 7:00 A.M. – 5:00 P.M.

Need for the Two New Locations

There is a need for additional MRI capacity in order to keep up with the existing demand in Hamden and Branford, and make MRI scanning part of the orthopedic process for the thirteen (13) new offices that have joined COS. The volume of scanning in the Hamden and Branford offices has been growing steadily over the last three years due to the increased number of patients at both locations. See **Exhibit B** for the volume increase from 2013 through June of 2016 (annualized).

The physicians in COS determined that the best way to offer MRI service to as many of the new COS patients as possible is to add a mobile unit which could service two distinct areas. Orange was selected as one location because it has six (6) COS offices within Orange and adjacent towns. Orange is close enough to Hamden that patients living between Orange and Hamden would be able to use Orange instead of driving north to Hamden if the wait in Hamden is too long.

The Essex location was selected because there is no COS MRI service anywhere near the three (3) new offices brought into the COS practice through the merger with Shoreline Orthopedic and Sports Medicine, which has offices in Essex, Guilford and Madison.

¹/ Prior to the 2014 and 2015 mergers with the 4 practices, the two COS MRIs each operated 64 hours per week (12 hours on Monday-Friday for and 4 hours on Saturdays).

In Orange

Depending upon where the patient lives, there will be many COS patients who are currently using the Branford or Hamden MRI who will find the Orange office more accessible for MRI scanning. This new mobile MRI would be able to accommodate COS patients who have been seeing their COS physician in the Orange, Milford, and Shelton physician offices which existed prior to the mergers. It will also be able to accommodate patients who have come in to the COS practice in the last two years as part of the merger with the Center for Orthopaedics, Orthopedic Health and The Orthopedic Group. Of the new orthopedic practices which have joined COS since 2014, one practice is located in Orange and two offices are located in Milford. All three offices are close enough to Orange to have their MRI scanning performed in the Orange office.

- The Center for Orthopedics has a practice in Orange located at 464 Boston Post Road, which is located 0.6 miles and 2 minutes from the existing COS office.
- The Orthopaedic Group has an office located in Milford at 30 Commerce Park which is 3.3 miles and 8 minutes away from the existing COS Orange office.
- Orthopedic Health has an office at 849 Boston Post Road in Milford which is located 6.8 miles and 15 minutes away from the existing Orange office.

There will be no facility fee involved in using the mobile MRI in Orange

In Essex

The Essex location would accommodate patients who had been seeing physicians in the Shoreline Orthopedics & Sports Medicine group which has offices in Essex, Guilford and Madison. This physician practice merged with COS in 2014. The orthopedic physicians in the Shoreline Orthopedics & Sports Medicine practice have three (3) offices. They are located in the following towns:

- Essex located at 12 Bokum Road.
- Madison located at 1353 Boston Post Road, which is 10.6 miles and 16 minutes from the Essex COS office.
- Guilford at which is 18.2 miles and 20 minutes from the COS Essex office.

By using this outpatient MRI service, it would be less costly as there is no facility fee, and all of the other benefits of having an in-practice MRI would also apply. COS patients would be able to have MRI scanning done in an outpatient facility, by a COS radiologist where the scans are read "stat", and transmitted to the treating orthopedic doctor either the same day, but no longer than 24 hours later.

Currently most patients who have been seeing doctors in the three (3) COS orthopedic groups in the Essex area who require an MRI study cannot be accommodated at an existing COS MRI and are referred to other providers for the MRI scan. The provision of a mobile MRI service in Essex would allow the patients of this COS orthopedic group to have the option of having any necessary MRI scan at a COS office. Many COS

patients who live in this service area (*See Table 2B, infra*) and currently have their MRI studies performed at a COS office in Hamden or Branford could have their MRI scans performed at the proposed Essex COS MRI, thereby improving accessibility to care.

The Implementation Timeline

If approved, the mobile MRI would begin installation immediately, and would be available to patients as soon as the installation is complete. It is anticipated that the mobile scanner would be operational within 90 days of approval.

2. Provide the history and timeline of the proposal (i.e., When did discussions begin internally or between Applicant(s)? What have the Applicant(s) accomplished so far?).

Response:

The Applicant was aware that in Hamden, the volume of scans rose from 304 scans in May of 2014 to 397 in October of 2014. It was apparent that the volume was growing, and COS began to add hours to their schedule for MRI scanning to keep up with the demand. In 2015, the volumes were again strong every month, with a maximum of 387 scans in October. (*See Exhibit B*).

In Branford, by 2015, the Applicant first realized that the number of scans being done there was also increasing. Between January and April of 2014, there were less than 200 MRI scans being performed each month. But in October of 2014, the volume rose to 275 per month. In October of 2015, Branford did 390 scans. It was at that point that COS began to feel the full effect of the four new orthopedic practices that had merged with COS and the effect on the MRI capacity it would need to keep pace with their physicians. (*See Exhibit B*).

Discussions began in late 2015 about adding a third MRI for the COS offices. Hours could not be expanded any further without significant added cost, and there simply was not enough space (slots) in the day and evening hours to add a significant number of scans. Sunday scanning was added in Hamden, which costs more due to overtime pay for skilled employees.

Currently in 2016, the volumes are growing even more rapidly. Hamden did 389 scans in March of 2016 and 382 scans in April of 2016. Branford did 409 scans in February of 2016, and 403 scans in March of 2016. And most recently, in June of 2016, 384 scans were performed in Hamden and 436 scans were performed in Branford. (*See Exhibit B*).

Thus far in 2016, Branford's monthly MRI volumes have been:

January: 378
February: 409
March: 403

April: 375
May: 392
June: 436

Hamden's volumes thus far in 2016 have been:

January: 359
February: 345
March: 389
April: 382
May: 355
June: 384

See Exhibit B.

The Applicant started working on a plan at the end of 2015, and has been working with its physicians and the vendors of MRI equipment to try to figure out the best solution. Both mobile and fixed MRIs were considered, and a decision was made in April that a mobile MRI to be shared by Orange and Essex would take the stress out of the existing schedules of Hamden and Branford, and the impossibility in the near future of accommodating even the Hamden and Branford patients for MRI scans within a reasonable period of time due to over-utilization. A mobile MRI will provide two locations, which will provide existing COS patients with better accessibility, while the new COS offices would have additional capacity for MRI scanning for their patients.

If approved, the mobile unit will operate in Orange on Mondays and Tuesday, travel to Essex on Wednesday and operate in Essex on Thursday and Friday. This will add 4 days of MRI scanning to the COS physician practice.

3. Provide the following information:

- a. utilizing OHCA Table 1, list all services to be added, terminated or modified, their physical location (street address, town and zip code), the population to be served and the existing/proposed days/hours of operation;

Response:

Please see OHCA Table 1.

- b. identify in OHCA Table 2 the service area towns and the reason for their inclusion (e.g., provider availability, increased/decreased patient demand for service, market share);

Response: Please see OHCA Table 2.

4. List the health care facility license(s) that will be needed to implement the proposal;

Response:

0 0 0 0 2 0

N/A No health care facility licenses will be required to implement the proposal because COS is a private physician practice.

5. Submit the following information as attachments to the application:

- a. a copy of all State of Connecticut, Department of Public Health license(s) currently held by the Applicant(s);

Response:

COS has a DPH license for its Out-Patient Surgical facility in Branford, which is attached as **Exhibit C**.

- b. a list of all key professional, administrative, clinical and direct service personnel related to the proposal and attach a copy of their Curriculum Vitae;

Response: Please see **Exhibit D**.

- c. copies of any scholarly articles, studies or reports that support the need to establish the proposed service, along with a brief explanation regarding the relevance of the selected articles;

Response: Please see **Exhibit E**.

- d. letters of support for the proposal;

Response: Please see **Exhibit F**.

- e. the protocols or the Standard of Practice Guidelines that will be utilized in relation to the proposal. Attach copies of relevant sections and briefly describe how the Applicant proposes to meet the protocols or guidelines.

Response: COS adheres to the American College of Radiology Standard of Practice Guidelines. In addition, COS has developed its own guidelines in a document entitled, "COS MRI Protocols/Guidelines" which is attached as **Exhibit G**.

- f. copies of agreements (e.g., memorandum of understanding, transfer agreement, operating agreement) related to the proposal. If a final signed version is not available, provide a draft with an estimated date by which the final agreement will be available.

Response:

N/A There is no other party involved in this application and therefore, no memorandum of understanding, transfer agreement or operating agreement.

Public Need and Access to Care

§ "Whether the proposed project is consistent with any applicable policies and standards adopted in regulations by the Department of Public Health;" (Conn.Gen.Stat. § 19a-639(a)(1))

6. Describe how the proposed project is consistent with any applicable policies and standards in regulations adopted by the Connecticut Department of Public Health.

Response:

Both existing MRI scanners have received accreditation from the American College of Radiology (copies of the certificates of accreditation are attached as **Exhibit H**). The MRI services are managed by Dr. Joseph Gagliardi, who is a full-time board certified radiologist and a member in good standing with the American College of Radiology. Dr. Gagliardi is also responsible for the written interpretation of the scans. ACR accreditation will be obtained for the proposed mobile MRI scanner and the proposed MRI service will also be managed by Dr. Gagliardi.

§ "The relationship of the proposed project to the statewide health care facilities and services plan;" (Conn.Gen.Stat. § 19a-639(a)(2))

7. Describe how the proposed project aligns with the Connecticut Department of Public Health Statewide Health Care Facilities and Services Plan, available on OHCA's website.

Response:

- a. The Applicant's proposal to add a 1.5 Tesla mobile MRI for its patients to be used in-office in Orange and Essex meets the requirements of the CT DPH OHCA Statewide Health Care Facilities and Services Plan both technically, and in the spirit of that document.

Existing Hamden and Branford MRIs

Between 2014 and 2015, COS added 13 new orthopedic physicians private offices to its practice, creating a large number of COS patients who will not be able to have an MRI scan at either Hamden or Branford due to the lack of extra capacity at either location. The need methodology set out in the CT DPH OHCA Statewide Health Care Facilities and Services Plan (p. 61), provides a benchmark of 4,000 scans for an MRI scanner and allows for the addition of a scanner if the existing scanner is operating over 85% capacity (3,400 scans annually). The two existing COS MRI scanners are currently operating at levels that exceed 85%, based on the OHCA benchmark of 4,000 scans per year. (See Table 5, infra).

In 2015, the MRI scanner in Hamden performed 3,773 scans which is 94% utilization of current capacity and is projected to have a 110% utilization of current capacity in 2016 (4,428 scans). Similarly, in 2015 the MRI scanner in Branford performed 3,851 scans which is 96% utilization of current capacity and is projected to have a 120% utilization of current capacity in 2016 (4,786 scans). *See Table 5, infra.* Therefore, the Applicant is in compliance with the standards as set forth in the CT DPH OHCA Statewide Health Care Facilities and Services Plan because these volumes exceed the 4,000 MRI scans per year benchmark contained in the plan.

In order to accommodate the current demand of COS patients for MRI scans, COS extended the hours of operation in 2016. Both scanners are now operating 75 hours per week. Although this is not ideal, it was necessary to enable COS to meet its patients' need for MRI scanning.

The Proposed Mobile MRI

The proposed mobile MRI scanner will initially operate four days per week with one weekday to travel (2 days in Essex and 2 days in Orange). The scanner will operate 12 hours per day at 45 minutes per scan, for a maximum of 32 scans per week or 1,664 scans per year at each location (total capacity of 3,328 MRI scans). If the scanner were to operate 5 days per week, it would have a total capacity of 4,160 MRI scans per year, which exceeds the 4,000 MRI scans per year benchmark contained in the CT DPH OHCA Statewide Health Care Facilities and Services Plan. In 2017, the projected utilization at the Orange location is 90% of the maximum capacity and at Essex it is 92% of the maximum capacity. In Orange the utilization increases to 93% in 2018 and 96% in 2019, while in Essex the utilization increases to 95% in 2018 and 98% in 2019. Based on the projected utilization, it is anticipated that the mobile MRI will need to be operated 5 days per week by 2018. *See Table 6 infra.*

- b. The application complies with the directive to maintain and improve the quality of health care services offered to the state's residents.

Dr. Gagliardi is a board certified radiologist who is a member in good standing with the American College of Radiology. He is able to read the MRI scans and report the findings back to the treating physician usually within the same day and no later than 24 hours after the MRI scan is done. Because this is a single-specialty orthopedic practice, the scanning process is more homogeneous, and Dr. Gagliardi has had years of experience with orthopedic scans. Patients appreciate the fact that they can have the MRI scan done in the doctor's office without having to travel to another location, and without waiting longer for the results. The time between MRI scanning and the orthopedic physician's ability to start treatment makes an enormous difference in the quality of the health care that is provided.

- c. The existing COS service and the proposed service will both be provided in the most cost effective way possible.

There is no facility fee involved. And COS has already begun the process of “bundling costs” so that the cost of an MRI scan is bundled with the other services that are necessary for the patient’s particular orthopedic diagnosis. This reduces the overall cost of the patient’s care. COS has already arranged with a couple of its major payers to offer this consolidated plan, and will reach out to all other payers who are interested in taking this step to reduce health care costs.

- d. The application promotes equitable access to health care services.

COS accepts both Medicare and Medicaid patients, and has recently adopted a Charity Care Policy that will facilitate the process of accepting patients who are unable to pay for access to necessary health care. See **Exhibit I**.

§ “Whether there is a clear public need for the health care facility or services proposed by the applicant;” (Conn.Gen.Stat. § 19a-639(a)(3))

- 8. With respect to the proposal, provide evidence and documentation to support clear public need:
 - a. identify the target patient population to be served;

Response:

Because this application is a proposal to add a mobile MRI for in-house use at private physician offices, the ordinary utilization calculation cannot be used. This MRI will not be dependent upon the ordinary service area calculation which is developed by setting up the service area, and then determining the number of people who would use the service, and whether there is already sufficient capacity in the service area or not. In this case, since the MRI unit that is requested will be used only for COS patients, the number of persons needing the service had to be calculated from the statistics of the COS facilities in the service areas for Orange and Essex (the two areas which will each have use of the mobile scanner 2 days a week).

The target population (as set forth in Tables 2A and 2B) is COS patients who live in either Essex or Orange, COS patients who live in all towns which are contiguous to either Essex or Orange, or towns that are adjacent to the contiguous towns in both locations which provide a significant COS patient volume. Since the mobile MRI will augment the existing COS MRI scanning capability in Hamden and Branford, the Applicant first utilized existing 2015 COS patient MRI data to determine the volume of CT COS patients in each of the service areas. This data is provided by patient zip code in **Exhibit J(1) – J(3)**

Exhibit J(1) is a compilation of zip code data identifying all COS patients living in Connecticut in 2015 who had an MRI scan at a COS scanner in Branford or Hamden. (There are many COS patients who live out-of-state, but they are not included in Exhibit J(1). See p.3 of Exhibit J(1) for the total volume in each service area. From this table, COS could determine how many of their patients live in the towns and contiguous towns where the new mobile MRI would be located. Exhibit J(2) is the compilation of zip code data identifying all COS patients who had an MRI scan at the existing MRI in Branford in 2015. This information was utilized to determine how many COS patients (already using one of the existing COS scanners) would find the mobile scanner either in Essex or Orange more accessible. And Exhibit J(3) is the compilation of zip code data identifying all COS patients who had an MRI scan at the existing MRI in Hamden in 2015 in order to estimate how many of these COS patients, (already being scanned on a COS scanner) would find either Orange or Essex more accessible.

The Applicant also used 2015 data regarding referrals of COS patients from the Essex area to non-COS MRI scanners as Shoreline Orthopedics had a list of all those patients who had been referred to non-COS facilities. The COS office in Orange did not have such a list, so a ratio was created to estimate the number of referrals of COS patients from the Orange area to non-COS MRI scanners (Exhibit L). From this combined information, COS could determine the number of COS patients that could not be accommodated at a COS facility in 2015, but were also likely to use the mobile scanner in either Essex or Orange.

- b. discuss how the target patient population is currently being served;

Response:

To the extent possible, the target population (which involves only COS patients) is currently served by the two COS MRI scanners that are located in Branford and Hamden. Prior to the addition of the 4 physician practices with 13 offices in 2014 and 2015, the COS patients could be accommodated by the 2 existing COS MRI scanners. However, since the size of the target population (COS patients) has increased as a result of the new practices, the COS MRI capacity has been exceeded. Due to the lack of COS MRI availability, most of the patients from the Shoreline Orthopedic offices are currently scanned at non-COS facilities. Please see the response to Question #2 for more detail.

- c. document the need for the equipment and/or service in the community;

Response:

The need for the proposed mobile MRI scanner is based on the current overutilization of the two existing MRI scanners. Both scanners are currently

operating over capacity. As described in the response to Question #1, both COS MRI scanners were operating 64 hours per week prior to 2015. In 2015 the Branford MRI scanner had a percent utilization of current capacity of 96% and the percent utilization of current capacity is projected to be 120% in 2016. The Hamden MRI had a 2015 percent utilization of current capacity of 94% and the percent utilization of current capacity is projected to be 110% in 2016. As a result of the increase in volume, COS was forced to extend the hours of operation of the MRI scanners to approximately 75 hours per week in order to accommodate the increase in MRI studies. Even operating at this level of over-utilization, COS cannot handle the existing or expected increase in patient volume.

The increase in utilization is due to the acquisition of 4 physician practices with thirteen offices. Impact of the acquisitions on MRI utilization at the existing COS scanners began in 2014 when COS experienced a 20% increase in the number of MRI scans performed. In 2015 COS experienced a 21% increase in the number of MRI scans, and the increase in the number of MRI scans is projected to be 21% in 2016.

Orange

As a result of the acquisition of Orthopedic Health, The Orthopedic Group and the Center for Orthopedics, COS now has six (6) physician offices in the Orange area. In 2015, the number of patients seen at the 6 offices had a combined total volume of 9,555 patients. See Exhibit L. Analysis of internal records based on patient records from all 21 COS offices in 2015 indicate that for every new COS patient, 1 out of every 6.38 patients required an MRI scan (15.6%) (See "Ratio Analysis" below the chart in Exhibit L.) This results in an estimated 1,488 scans generated by patients seen at the 6 COS offices in the Orange area offices. See Exhibit L.

The influx of patients from these practices has saturated the capacity of the existing MRI scanners. In 2015, while 1041 patients were able to be scanned on one of the two existing MRIs, an estimated 447 patients of the COS offices in the Orange area could not be accommodated at a COS MRI and were referred to another provider for MRI scan. See Exhibit L.

Essex

The Shoreline Orthopedics and Sports Medicine practice has offices in Essex, Madison and Guilford. Currently most patients who see doctors in this COS orthopedic group who require an MRI study cannot be accommodated at an existing COS MRI and are referred to other providers for the MRI study. In 2015, the Shoreline Orthopedic practice referred 963 patients, including 569 patients from the Essex service area, to non-COS MRI facilities. See Exhibit K.

Additionally, 950 patients who lived in the Essex service area in 2015 and were treated at COS offices other than Shoreline Orthopedics offices received an MRI scan at either the Branford or Hamden MRI scanners in 2015. See Exhibit J(1), p.3. A total of 1,519 COS patients from the service area received an MRI scan in 2015 (950 at a COS MRI and 569 referred to a non-COS MRI scanner). The 950 COS patients who live in the Essex service area and were scanned at either the COS Branford MRI or the COS Hamden MRI in 2015 will likely utilize the Essex mobile MRI if it is approved.

- d. explain why the location of the facility or service was chosen;

Response:

COS might have sought approval from OHCA to add one (1) additional fixed MRI at either its Branford or Hamden location. However, the decision was made to locate the additional MRI in the locations where the service is most needed. Essex was selected as one of the two locations to offer MRI service two days a week because of the influx of new patients in the shoreline area with the addition of Shoreline Orthopedics & Sports Medicine ("Shoreline") to COS. Shoreline has offices in Essex, Madison and Guilford. Orange was selected as the other site for the additional MRI service because of the volume of scanning at the Hamden and Branford offices and the accessibility it would offer to COS patients well within travel time to use the Orange location depending upon where they live in relation to the service in Orange. These are COS patients currently using a COS MRI who will now transfer to the mobile MRI in Orange.

- e. provide incidence, prevalence or other demographic data that demonstrates community need;

Response:

As discussed in the responses to Questions #1 and #8c, COS is an established orthopedic practice that provides MRI scanning to its patients as part of the continuum of orthopedic treatment. COS scanning services are not available to non-COS patients. The need for mobile MRI services is due to the overutilization of the 2 existing scanners in Hamden and Branford and to the addition of the 4 physician practices which has 13 offices in Connecticut which are now COS physician practices. COS now has 21 physician offices. The two existing scanners can no longer handle the volume that is required. See Exhibit A for a map of the total number of COS locations. COS has extended the normal hours of operation in Hamden and Branford to meet patient need, and is still unable to accommodate all its patients who require an MRI scan at its 2 existing MRI locations.

- f. discuss how low income persons, racial and ethnic minorities, disabled persons and other underserved groups will benefit from this proposal;

Response:

Racial and ethnic minorities are not discriminated against by COS. Physically disabled persons are accommodated with every means available because these patients are coming to COS with an orthopedic problem, which can be very disabling. Mentally disabled persons are encouraged to bring a person with them to the appointments so that they have the support they need in understanding directions to follow. COS has recently adopted a Charity Care Plan to assist low income and underserved groups. *See Exhibit I.*

- g. list any changes to the clinical services offered by the Applicant(s) and explain why the change was necessary;

Response:

There will be no changes to the clinical services offered by COS as a result of this application.

- h. explain how access to care will be affected;

Response:

Access to MRI services will be greatly improved for COS patients who live in the Essex and Orange area. These patients will be able to be accommodated at a COS office location on a more timely basis; the patient will not have to seek MRI services at a different location unless they choose to do so.

- i. discuss any alternative proposals that were considered.

Response:

The only alternative that was considered by COS was a fixed MRI. Ultimately a mobile MRI unit was selected so that the service will match up with the two geographical areas where there is the greatest need for COS patients to have MRI scanning. The service is being tailored to the specific patient need.

§ "Whether the applicant has satisfactorily demonstrated how the proposal will improve quality, accessibility and cost effectiveness of health care delivery in the region, including, but not limited to, (A) provision of or any change in the access to services for Medicaid recipients and indigent persons; (Conn.Gen.Stat. § 19a-639(a)(5))

9. Describe how the proposal will:

- a. improve the quality of health care in the region;

Response:

For COS patients living along the shoreline between Guilford and Essex, having MRI scanning available at a COS office in Essex will provide better access to MRI scanning than having to drive to Branford (which is the closest COS office with an MRI unit). For patients in the Orange area, the MRI service two days a week will facilitate having the scans performed closer to home than Hamden or Branford, where the closest COS scanning is performed. Drive time can be an important factor for orthopedic patients depending upon what part of the body has been injured or is otherwise in need of medical attention.

The coordination between the COS radiologist and the COS physician is seamless. And the MRI scanning results can be delivered much faster than from another facility. And for many of the orthopedic patients who are being treated by a COS physician, the cost of MRI scanning is built into the cost of their treatment. It is not a separate bill.

- b. improve accessibility of health care in the region; and

Response:

Since the Applicant is a private physician practice, its patients have been using the 2 MRI units in Branford and Hamden without any issues of accessibility until the last year. With the addition of the 4 new physician practices between 2014 and 2015, the 2 COS MRIs are now over capacity. Adding 4 days of MRI scanning in two new locations will make MRI service much more accessible for COS patients in the Essex and Orange areas.

- c. improve the cost effectiveness of health care delivery in the region.

Response:

COS has arranged with a couple of its major commercial insurers to pay one fixed price for a patient's entire treatment for the orthopedic diagnosis the patient presents. For example, if a patient comes to COS with an anterior cruciate ligament ("ACL") injury, there is a fixed price that COS will receive no matter how much care the patient receives. This fixed fee is a bundling of the individual fees.

The ACL patient's one bill will include the physician's care, the use of the facility, (physician's office and surgical center, if required) surgery, and the costs associated with the surgery (anesthesiologist, etc.) and radiology costs, including the fee for the radiologist. Whether the patient needs an X-ray, or an MRI or both, or multiple x-rays or scans or surgery and the use of the outpatient surgical center, the price remains the same. The fixed fee also includes physical therapy if the patient requires it. This is an incentive for the physician to carefully select the tools needed to resolve the patient's problem, and not over utilize the technology

that is available. COS measures the costs involved in treatment, and compares the costs with patient outcomes. This system is known as “Time-Driven Activity Based Costing” or “TDABC”. Please see Exhibit E, “The Big Idea, How to Solve the Cost Crisis in Health Care”, Harvard Business Review, Sept. 2011. This system creates efficiency and lowers the cost of treatment, while maintaining the highest quality.

10. How will this proposal help improve the coordination of patient care (explain in detail regardless of whether your answer is in the negative or affirmative)?

Response:

This proposal will help to improve the coordination of patient care because the patient is being treated under the direction of one physician. If MRI scanning is required, the appointment is set up by the treating orthopedic physician. The radiologist who reads the MRI scan is an employee of COS, and is focused on reading COS scans within hours of receiving them. The radiologist communicates directly with the patient’s treating doctor. If the patient needs outpatient surgery this can be done in the COS outpatient surgery center in Branford. If the patient needs surgical care in a hospital, that is also arranged by, and performed by the COS orthopedic surgeon. This coordination is extremely helpful to the patients who are suffering with orthopedic problems, and who often need medical care as quickly as possible.

11. Describe how this proposal will impact access to care for Medicaid recipients and indigent persons.

Response: Medicaid recipients are accepted at all COS facilities. Indigent persons will be treated under the COS charity care policy.

12. Provide a copy of the Applicant’s charity care policy and sliding fee scale applicable to the proposal.

Response: See Exhibit I.

§ "Whether an applicant, who has failed to provide or reduced access to services by Medicaid recipients or indigent persons, has demonstrated good cause for doing so, which shall not be demonstrated solely on the basis of differences in reimbursement rates between Medicaid and other health care payers;" (Conn.Gen.Stat. § 19a-639(a)(10))

13. If the proposal fails to provide or reduces access to services by Medicaid recipients or indigent persons, provide explanation of good cause for doing so.

Response: N/A

§ "Whether the applicant has satisfactorily demonstrated that any consolidation resulting from the proposal will not adversely affect health care costs or accessibility to care." (Conn.Gen.Stat. § 19a-639(a)(12))

14. Will the proposal adversely affect patient health care costs in any way? Quantify and provide the rationale for any changes in price structure that will result from this proposal, including, but not limited to, the addition of any imposed facility fees.

Response:

This proposal should benefit patient health care costs in a positive way as COS encourages all of its payers to participate in a "bundled payment" program. MRI scanning fees will remain the same, and there will be no facility fees at any COS location.

Financial Information

§ "Whether the applicant has satisfactorily demonstrated how the proposal will impact the financial strength of the health care system in the state or that the proposal is financially feasible for the applicant;" (Conn.Gen.Stat. § 19a-639(a)(4))

15. Describe the impact of this proposal on the financial strength of the state's health care system or demonstrate that the proposal is financially feasible for the applicant.

Response:

This proposal will positively impact the financial strength of the state's health care system because COS will be offering its patients more cost effective collaborative MRI scans. Additionally, this proposal is financially feasible for COS because COS has a proven track record by fully utilizing its existing scanners and it has the utilization numbers to support the proposed mobile MRI scanner.

16. Provide a final version of all capital expenditure/costs for the proposal using **OHCA Table 3**.

Response: See OHCA Table 3 and **Exhibit M**

17. List all funding or financing sources for the proposal and the dollar amount of each. Provide applicable details such as interest rate; term; monthly payment; pledges and funds received to date; letter of interest or approval from a lending institution.

Response: See **Exhibit N**.

18. Include as an attachment:

- a. audited financial statements for the most recently completed fiscal year. If audited financial statements do not exist, provide other financial documentation (e.g., unaudited balance sheet, statement of operations, tax return, or other set of books). Connecticut hospitals required to submit annual audited financial statements may reference that filing, if current;

Response: See **Exhibit O**.

- b. completed **Financial Worksheet A (non-profit entity), B (for-profit entity) or C (\$19a-486a sale)**, available on OHCA's website under OHCA Forms, providing a summary of revenue, expense, and volume statistics, "without the CON project," "incremental to the CON project," and "with the CON project." **Note: the actual results reported in the Financial Worksheet must match the audited financial statement that was submitted or referenced.**

Response: See **Exhibit P**.

19. Complete **OHCA Table 4** utilizing the information reported in the attached Financial Worksheet.

Response: See Table 4 in Section on Tables *infra*.

20. Explain all assumptions used in developing the financial projections reported in the Financial Worksheet.

Response: See **Exhibit Q**.

21. Explain any projected incremental losses from operations resulting from the implementation of the CON proposal.

Response: No projected incremental losses from operations are expected from the implementation of this CON proposal.

22. Indicate the minimum number of units required to show an incremental gain from operations for each projected fiscal year.

Response:

For FY2017, the minimum number of units to show an incremental gain would be 440 scans, for 2018, it would be 707 scans and for 2019 it would be 977 scans.

Utilization

§ "The applicant's past and proposed provision of health care services to relevant patient populations and payer mix, including, but not limited to, access to services by Medicaid recipients and indigent persons;"
(Conn.Gen.Stat. § 19a-639(a)(6))

23. Complete **OHCA Table 5** and **OHCA Table 6** for the past three fiscal years ("FY"), current fiscal year ("CFY") and first three projected FYs of the proposal, for each of the Applicant's existing and/or proposed services. Report the units by service, service type or service level.

Response: Please see **OHCA Table 5** and **OHCA Table 6**, *infra*.

24. Provide a detailed explanation of all assumptions used in the derivation/ calculation of the projected service volume; explain any increases and/or decreases in volume reported in OHCA Table 5 and 6.

Response:

Assumptions Used in Table 5: Increases in Volume

COS has experienced significant increases in utilization from 2013 to 2015. The increase is projected to continue into 2016. The increases in utilization are as follows:

2013 - 2014	20.4% increase
2014 - 2015	21% increase
2015 - 2016	21% increase (projected)

The increases that occurred between 2013 and 2016 (through June) are due to two factors, the merger of four existing physician practices into COS and an increase in the hours of operation. (Please see response to Question 1 for more detail on the mergers, the impact on volume, and extended hours of operation). The rate of increase is anticipated to slow in 2017 due to the "maturation" of the merger (with the exception of the patients from the Shoreline Orthopedics & Sports Medicine who are still being referred to other providers).

Assumptions used in OHCA Table 6

Overall Assumptions

- An MRI scan takes 45 minutes.
- The optimum use rate for each scanner is 85% of the maximum number of scans possible within the scheduled hours of operation. This allows the scheduling for maintenance, downtime, cancellations and holidays, etc.
- The MRI scanners located in Hamden and Branford will operate 64 hours per week (Monday – Friday for 12 hours per day and 4 hours on Saturday) for a maximum of 85 scans per week or 4,420 scans per year. At an 85% use rate, the number of scans for each scanner on an annual basis is 3,757 scans. (This represents a reduction in hours of operation and number of scans currently performed at these locations).
- The reduction in the volume at Hamden and Branford will bring these scanners back to a normal, maximum use rate, and the overflow of patients is expected to utilize the mobile units in Orange and Essex.
- Initially, the mobile MRI scanner will operate 2 days per week in Orange and 2 days per week in Essex. The scanner will operate 12 hours per day at each location (a maximum of 32 scans per week or 1664 scans per year at each location). At an 85% use rate, the number of scans at each location in 2017 is 1414 (1664 scans x 85%).
- The annual rate of increase in MRI volume at each of the four locations for 2018 to 2019 is 3%. This is based on the historic rate of increase experienced by the Applicant prior to the mergers of physician practices. Between 2012 and 2013, the rate of increase was 2.7%. *See OHCA Table 5.*
- In 2019 a third day of scanning can be added, if necessary, to either the Essex office or the Orange office depending upon which location has the largest volume of MRI scanning.

Essex Mobile MRI Assumptions

- The 2015 volume of COS patients from the Essex service area who received an MRI scan serves as the base for the projected utilization. Of the total 1,519 COS patients who received an MRI scan, 950 COS patients received an MRI scan at a COS MRI scanner and 569 were referred to a non-COS MRI. (Please see Table 8b, “Utilization by Town” and Exhibits J(1) & K.

- An annual rate of increase in volume of 3% was applied to the 2015 MRI volume for 2016 and 2017.
- It is assumed that approximately 5% of the patients residing in the Essex service area will utilize either the Branford or Hamden MRI as they have in the past.

Orange Mobile MRI Assumptions

- An analysis of COS internal records for 2015 for 6 COS offices in Orange, Shelton and Milford was undertaken. Three of these are original COS offices (Orange, Shelton and Milford) and three are from the merger (one in Orange and two in Milford). It is assumed that the persons most likely to use the Orange MRI are residents of these towns or patients who use the COS offices in these towns.
 - Based on the review of COS internal records for 2015, it is estimated that 9,555 new patients were seen at these offices and 15.6% required an MRI study (1,488 patients). 1,041 of these patients were accommodated at the COS Branford or Hamden MRI scanner and 447 were referred to a non-COS MRI. These 1,488 COS patients serve as the base for the projected utilization. *See Table #8a and Exhibit L.*
 - An annual rate of increase in volume of 3% was applied to the 2015 MRI volume for 2016 and 2017.
 - It is assumed that approximately 5% of the 1,488 COS patients will utilize either the Branford or Hamden MRI as they have in the past.
25. Provide the current and projected patient population mix (number and percentage of patients by payer) for the proposal using **OHCA Table 7** and provide all assumptions. **Note: payer mix should be calculated from patient volumes, not patient revenues.**

Response: Please see OHCA Table 7, infra.

The patient population mix is based on COS actual experience in 2015 and 2016, year to date. The patient population mix is not expected to change as a result of this proposal.

§ "Whether the applicant has satisfactorily identified the population to be served by the proposed project and satisfactorily demonstrated that the identified population has a need for the proposed services;"
(Conn.Gen.Stat. § 19a-639(a)(7))

26. Describe the population (as identified in question 8(a)) by gender, age groups or persons with a specific condition or disorder and provide evidence (i.e., incidence, prevalence or other demographic data) that demonstrates a need for the proposed service or proposal. **Please note: if population estimates or other demographic data are submitted, provide only publicly available and verifiable information (e.g., U.S. Census Bureau, Department of Public Health, CT State Data Center) and document the source.**

Response:

As stated above in the response to Question 8(a), the target population to be served is COS's existing orthopedic patient base. Based on the overutilization of the two existing MRI scanners, and the expansion of COS orthopedic offices from eight (8) to twenty-one (21), the COS current patient base is sufficiently large to support the addition of a mobile CON without demonstrating additional need.

27. Using **OHCA Table 8**, provide a breakdown of utilization by town for the most recently completed fiscal year. Utilization may be reported as number of persons, visits, scans or other unit appropriate for the information being reported.

Response: Please see **OHCA Table 8, *infra.***

§ "The utilization of existing health care facilities and health care services in the service area of the applicant;" (Conn.Gen.Stat. § 19a-639(a)(8))

28. Using **OHCA Table 9**, identify all existing providers in the service area and, as available, list the services provided, population served, facility ID (see table footnote), address, hours/days of operation and current utilization of the facility. Include providers in the towns served or proposed to be served by the Applicant, as well as providers in towns contiguous to the service area.

Response: Please see **OHCA Table 9, *infra.***

29. Describe the effect of the proposal on these existing providers.

Response:

The effect on existing providers should be minimal. There will only be two days a week of scanning in each location, and the two locations are far apart geographically. Most of the patients who will be using the new mobile scanner are patients who have gone to the Hamden or Branford COS locations for MRI scanning in the past because they are either patients who see a COS physician in one of those two offices, or they are COS patients from other offices who live close enough to Hamden or Branford to use either of those two locations. With more capacity to ease the over-capacity issue at both of these locations, no other provider should be greatly affected by the change

in location of these patients. These patients will have their MRI scanning done in Orange or Essex if Hamden or Branford are over capacity.

For the COS patients who have had to use other providers in the past, COS will be recapturing its own patients so that their treatment can be delivered under the direction of one orthopedic specialist. However, all COS patients have the option of using any other radiology service that provides MRI scanning if they want to, or if the COS MRI is not accessible to them. For COS patients in the Essex area who have used another radiology provider prior to becoming COS patients (the Shoreline patients), the geographic area where these patients live is so large that no one existing provider should be more than minimally impacted. It is assumed that claustrophobic or obese patients will continue to be scanned by providers with open MRI scanners.

If a COS patient decides to use another provider for the MRI scan, and the patient's insurer participates in the COS "bundling of costs", COS will contact the other provider to let that office know that the MRI scan is already paid for since it is one of the payments bundled together for a single payment to COS. Arrangements will be made for COS to pay the other provider on behalf of the patient.

30. Describe the existing referral patterns in the area served by the proposal.

Response:

COS physicians are the sole referral for the two existing MRI scanners. There is no publically available data on existing referral patterns for other physicians in the service area.

31. Explain how current referral patterns will be affected by the proposal.

Response:

Current referral patterns will not change as COS physicians continue to be the sole referral source for the two existing MRI scanners and the proposed MRI scanner. It is anticipated that the proposal will have no effect on non-COS referring physicians as COS will be able to accommodate future patient base growth.

§ "Whether the applicant has satisfactorily demonstrated that the proposed project shall not result in an unnecessary duplication of existing or approved health care services or facilities;" (Conn.Gen.Stat. § 19a-639(a)(9))

32. If applicable, explain why approval of the proposal will not result in an unnecessary duplication of services.

Response:

This is a request for in-office MRI scanning for patients who have already chosen a COS orthopedic specialist. It is anticipated that the mobile MRI will take stress off the two existing COS scanners who which have no hours left in the week that are reasonable to offer more capacity. COS has the patient population that could fill up the slots available on the new mobile MRI within two years. Immediately, COS patients who live in Orange, Milford or Shelton, or use the COS offices in Orange, Milford or Shelton and have been using the Branford MRI or the Hamden MRI will be able to switch over to the closer location. Those patients along the shoreline and in Essex who are COS patients will undoubtedly switch from the COS Branford MRI to the Essex location. Since the mobile MRI is for the use of COS patients only, it should not have the same effect as opening a new imaging center or a new radiology center with MRI capacity. The COS patients are already established. And for them, it is makes more sense to use the MRI services that are already connected to the rest of their treatment, and possibly included in their fee for treatment.

§ *“Whether the applicant has satisfactorily demonstrated that the proposal will not negatively impact the diversity of health care providers and patient choice in the geographic region;” (Conn.Gen.Stat. § 19a-639(a)(11))*

33. Explain in detail how the proposal will impact (i.e., positive, negative or no impact) the diversity of health care providers and patient choice in the geographic region.

Response:

For some patients, having MRI scanning for an orthopedic medical condition is more suited, or necessary, in a hospital location. For others patients, who have not yet selected an orthopedic physician, they may get a referral from a primary care doctor and have the MRI scan done at an outpatient clinic or imaging center operated by a radiologist.

For those patients already seeing an orthopedic physician, MRI scanning done by the same physician practice makes sense. At COS practices, in-office scanning is scheduled immediately and the results are back to the treating physician within 24 hours of the MRI scan. Also at COS, the fee for the MRI scan can be bundled in with the other costs of treatment so that it saves costs for the patient, depending upon the insurer.

This diversity is healthy for Connecticut patients because there is a choice of how to have MRI scanning done. Finding the right practitioner or facility for the patient’s specific medical condition as early as possible leads to better treatment for the patient and potentially less expensive treatment later.

Tables

**TABLE 1
APPLICANT'S PROPOSED SERVICES AND SERVICE LOCATIONS**

ORANGE AND ESSEX

Service	Street Address, Town	Population Served	Days/Hours of Operation	New Service or Proposed Termination
Adding 2 days of MRI Scanning at Existing COS Office	330 Boston Post Road Orange, CT 06477	COS patients	7:00 am – 7:00 pm Monday & Tuesday	COS Mobile MRI
Adding 2 days of MRI Scanning at Existing COS Physician Office f/k/a Shoreline Orthopedics & Sports Medicine	12 Bokum Road Essex, CT 06426	COS Patients	7:00am – 7:00pm Thursday & Friday	COS Mobile MRI

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**TABLE 2A
ORANGE
SERVICE AREA TOWNS**

List the official name of town* and provide the reason for inclusion.

Town*	Reason for Inclusion
<p style="text-align: center;">Orange New Haven Woodbridge Shelton Derby West Haven Milford Stratford East Haven North Haven</p>	<p>The service area consists of Orange, the site of the proposed mobile MRI scanner for 2 days a week, the towns that are contiguous to Orange (Milford, West Haven, New Haven, Woodbridge, Derby, and Shelton), and North Haven, East Haven and Stratford which are contiguous with other service area towns. North Haven, East Haven and Stratford are included in the service area because residents of these towns are a significant part of the volume at the existing Orange COS facility. In 2015 3,049 residents of these towns received a MRI scan at a COS facility. It is anticipated that the mobile scanner will provide access for the COS patients who use the existing Orange, Milford, Shelton and New Haven offices as well as the new COS offices which are located in Orange and Milford.</p>

* Village or place names are not acceptable

In 2015, 3049 residents of the service area received an MRI scan at a COS facility. See **Exhibit J (1)**, p.3. Additionally, the Applicant is able to estimate that approximately 447 patients from the COS offices located in Orange, Milford and Shelton were referred to non-COS providers for MRI scans. See **Exhibit L**.

Hamden has not been included in the service area because a COS MRI scanner is located in Hamden and that scanner has its own COS service area.

**TABLE 2B
ESSEX
SERVICE AREA TOWNS**

List the official name of town* and provide the reason for inclusion.

Town*	Reason for Inclusion
<p style="text-align: center;">Essex</p> <p style="text-align: center;">Madison</p> <p style="text-align: center;">Guilford</p> <p style="text-align: center;">Clinton</p> <p style="text-align: center;">Old Saybrook</p> <p style="text-align: center;">Westbrook</p> <p style="text-align: center;">Old Lyme</p> <p style="text-align: center;">Deep River</p> <p style="text-align: center;">Chester</p>	<p>The service area consists of Essex, the site of the proposed mobile MRI scanner for 2 days a week, Madison and Guilford which are the site of other COS physician offices, f/k/a Shoreline Orthopedics & Sports Medicine, and the towns that are contiguous to Essex. Chester was also included in the service area because of the number of external referrals for MRI scans. It is anticipated that the mobile scanner will provide access to the new COS offices which are located in Essex, Madison and Guilford.</p>

* Village or place names are not acceptable.

In 2015, 950 residents of the COS Essex service area received an MRI scan at a COS facility. See Exhibit J (1), p.3.. Additionally, the new COS office in Essex (f/k/a Shoreline Orthopedics & Sports Medicine) referred 569 residents of the COS service area patients to a non-COS facility. The referrals out of that office to other providers for MRI scanning are listed in Exhibit K, p.2..

**TABLE 3
TOTAL PROPOSAL CAPITAL EXPENDITURE**

Purchase/Lease	Cost
Equipment (Medical, Non-medical, Imaging)	\$ 575,000.00
Land/Building Purchase*	
Construction/Renovation**	\$ 730,000
Other (specify)	
Total Capital Expenditure (TCE)	\$ 730,000
Lease (Medical, Non-medical, Imaging)***	
Total Lease Cost (TLC)	
Total Project Cost (TCE+TLC)	\$ 730,000

* If the proposal involves a land/building purchase, attach a real estate property appraisal including the amount; the useful life of the building; and a schedule of depreciation.

** If the proposal involves construction/renovations, attach a description of the proposed building work, including the gross square feet; existing and proposed floor plans; commencement date for the construction/ renovation; completion date of the construction/renovation; and commencement of operations date.

*** If the proposal involves a capital or operating equipment lease and/or purchase, attach a vendor quote or invoice; schedule of depreciation; useful life of the equipment; and anticipated residual value at the end of the lease or loan term

A copy of the Purchase Agreement for the MRI and an estimate for the trailer installations are attached in Exhibit N.

**TABLE 4
PROJECTED INCREMENTAL REVENUES AND EXPENSES**

	FY 2017*	FY 2018*	FY 2019*
Revenue from Operations	\$ 801,262	\$ 992,096	\$ 1,187,746
Total Operating Expenses	\$ 497,687	\$ 525,314	\$ 554,975
Gain/Loss from Operations	\$ 303,575	\$ 466,782	\$ 632,771

*Fill in years using those reported in the Financial Worksheet attached.
Note: COS Fiscal Year is Jan.1-Dec.31 (calendar year)

**TABLE 5
HISTORICAL UTILIZATION BY SERVICE**

MRI Service	Actual Volume MRI Scans (Last 4 Completed FYs)				CFY Volume*
	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Connecticut Orthopaedic Specialists 84 North Main Street Branford, CT (MRI)	2,886	2,095	2,577	3,851	4,786
Connecticut Orthopaedic Specialists 2416 Whitney Ave Hamden, CT (MRI)	2,214	3,141	3,725	3,773	4,428
Total	5,100	5,236	6,302	7,624	9,214

• Annualized based on first 6 months of FY 2016

Note: This data does not include the COS patients who could not be scanned at the COS scanners in Branford or Hamden due to the lack of capacity at those locations. The estimated number of COS patient who could not be scanned at a COS facility in 2015 was 1,016 and in 2016 is projected to be 1,046.

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**TABLE 6
PROJECTED UTILIZATION BY SERVICE**

Existing MRI Service	Projected Volume MRI Scans		
	FY 2017	FY 2018	FY 2019
Connecticut Orthopaedic Specialists 84 North Main Street Branford, CT (MRI)	3,757	3,870	3,986
Connecticut Orthopaedic Specialists 2416 Whitney Avenue Hamden, CT (MRI)	3,757	3,870	3,986
Proposed MRI Service			
Connecticut Orthopaedic Specialists 330 Boston Post Road, Orange (MRI)	1,500	1,545	1,591
Connecticut Orthopaedic Specialists 12 Bokum Road, Essex, CT (MRI)	1,531	1,577	1,624
Total	10,545	10,862	11,187

* Identify each service type by location and add lines as necessary. Provide the number of visits/discharges as appropriate for each service listed.

** If the first year of the proposal is only a partial year, provide the first partial year and then the first three full FYs. Add columns as necessary. If the time period reported is not *identical* to the fiscal year reported in Table 4 of the application, provide the date range using the mm/dd format as a footnote to the table.

Note: The volumes for COS MRIs performed in Branford and Hamden have been scaled back from their volumes in 2015 and 2016. This is due to the expected number of COS patients who live closer to Orange than to Hamden or Branford and will likely use the new

mobile scanner in Orange. It also reflects the likely use of the mobile scanner in Essex by COS patients who live in the Essex service area and not had access to a COS scanner closer than Branford.

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**TABLE 7
APPLICANT'S CURRENT & PROJECTED PAYER MIX**

Payer	Current FY 2016		Projected					
	Discharge s	%	FY 2017		FY 2018		FY 2019	
			Discharge s	%	Discharge s	%	Discharge s	%
Medicare*	1,659	18%	1,898	18%	1,955	18%	2,014	18%
Medicaid*	64	0.7%	74	0.7%	76	0.7%	78	0.7%
CHAMPUS & TriCare								
Total Government	1,723	18.7%	1,972	18.7%	2,031	18.7%	2,092	18.7%
Commercial Insurers	6,358	69%	7,276	69%	7,495	69%	7,719	69%
Uninsured	37	0.4%	42	0.4%	43	0.4%	45	0.4%
Workers Compensation	1096	11.9%	1255	11.9%	1,293	11.9%	1,331	11.9%
Total Non- Government	7,491	81.3%	8,573	81.3%	8,831	81.3%	9,095	81.3%
Total Payer Mix	9,214	100%	10,545	100%	10,862	100%	11,187	100%

* Includes managed care activity.

**TABLE 8A
COS ORANGE
UTILIZATION BY TOWN**

Town	COS MRI FY 2015*
Orange	232
New Haven	626
West Haven	517
Milford	503
Woodbridge	158
Shelton	56
Derby	35
North Haven	416
East Haven	450
Stratford	56
Total	3,049

*Number of patients from the Orange service area receiving MRI scans performed on Hamden or Branford COS MRI scanner in 2015. See Exhibit J (1), P 3.

**TABLE 8B
ESSEX
UTILIZATION BY TOWN**

Town	COS MRI FY 2015*	COS MRI External Referrals FY 2015**	Total MRI FY 2015
Essex	12	120	132
Madison	299	64	363
Clinton	121	6	127
Old Saybrook	39	141	180
Westbrook	33	77	110
Old Lyme	28	107	135
Deep River	12	1	13
Chester	8	40	48
Guilford	398	13	411
Total	950	569	1,519

*Number of patients from primary service area receiving MRI scans performed on Hamden or Branford COS MRI scanner. See **Exhibit J(1), p.3.**

Number of patients from primary service area that Shoreline Orthopedics & Sports Medicine referred to other locations for MRI. These patients will be able to utilize the COS Essex Mobile MRI. The data on the referrals is from the electronic medical record system used by Shoreline Orthopedics & Sports Medicine. It is not known where these patients received their MRI, only that their COS physician gave the patients an order to have an MRI scan performed. See **Exhibit K., pp. 1-2.

**TABLE 9
SERVICES AND SERVICE LOCATIONS OF EXISTING PROVIDERS**

ORANGE, CT

Service or Program Name	Population Served	Facility ID*	Facility's Provider Name, Street Address and Town	Hours/Days of Operation	Current Utilization
1.5 T Fixed, Closed	Not publically available	Not publically available	Milford Hospital, Inc. 300 Seaside Avenue Milford, CT 06460	24 hours/day, 7 days/week	2005 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Griffin Hospital 130 Division Street Derby, CT	Monday, Wednesday & Friday 7:00am - 7:00pm Saturday 7:00am- 2:00pm	1888 scans in 2013
1.2 T Mobile, Closed	Not publically available	Not publically available	Griffin Imaging and Diagnostic Center at Ivy Brook 2 Ivy Brook Road Shelton, CT 06484	Monday - Friday 7:30am - 6:00pm	2341 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. d/b/a New Haven-Main Campus 20 York Street, New Haven 06510	Sunday- Saturday 24 hours	4010 scans in 2013
1.5T	Not publically	Not	Yale-New Haven Hospital, Inc. d/b/a	Sunday-	4454 scans

Fixed, Closed	available	publicly available	New Haven-Main Campus 20 York Street, New Haven 06510	Saturday 24 hours	in 2013
3.0T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. d/b/a New Haven-Main Campus 20 York Street, New Haven 06510	Sunday-Saturday 24 hours	4020 scans in 2013
3.0T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. d/b/a New Haven-Main Campus 20 York Street, New Haven 06510	Sunday-Saturday 24 hours	2556 scans in 2013
3.0T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. d/b/a New Haven-Main Campus 20 York Street, New Haven 06510	Sunday-Saturday 24 hours	6231 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. d/b/a New Haven-Main Campus 20 York Street, New Haven 06510	Sunday-Saturday 24 hours	6130 scans in 2013
3.0T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. d/b/a New Haven-Main Campus 20 York Street, New Haven 06510	Sunday-Saturday 24 hours	6003 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. at Chapel Street Campus 1450 Chapel Street, New Haven 06511	Sunday-Saturday 24 hours	812 scans in 2013
3.0T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. at Chapel Street Campus 1450 Chapel Street, New Haven 06511	Sunday-Saturday 24 hours	713 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. (Temple Radiology New Haven) 60 Temple Street, New Haven 06510	Monday-Friday 8:30-4:30	2582 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Saint Raphael Magnetic Resonance Center 330 Orchard Street, New Haven 06511	Monday – Friday 6:30am – 10:30pm	1827 scans in 2013
1.5 T Fixed, Closed	Not publically available	Not publically available	Bridgeport Hospital 2595 Main Street Stratford, CT 06615	Monday – Friday 8:00am – 5:00pm	1492 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Bridgeport Hospital 267 Grant Street Bridgeport, CT 06610	24 hours per day, 7 days per week	3,500 scans in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	St. Vincent's Medical Center 2800 Main Street Bridgeport, CT 06606	24 hours per day, 7 days per week	4,277 scans in 2013
3 T Fixed, Open	Not publically available	Not publically available	Advanced Radiology Consultants, LLC 297 Boston Post Road Orange, CT 06477	Monday-Friday 8:30am – 5:00 pm, Saturday 8:30am-12:00pm	3114 scans in 2013
1.5 T Fixed, Closed	Not publically available	Not publically available	Advanced Radiology Consultants, LLC	Monday – Friday	5,700 scans in 2013

		available	2876 Main Street Stratford, CT 06614	7:00am- 11:00pm Saturday – Sunday 7:00am – 7:00pm	
1.5 T Fixed, Closed	Not publically available	Not publically available	Advanced Radiology Consultants, LLC 4 Corporate Drive Shelton, CT 06484	Monday – Friday 8:30am – 5:00pm	3,975 scans in 2013
1.5T Fixed, Open	Not publically available	Not publically available	Advanced Radiology Consultants, LLC 15 Corporate Drive Trumbull, CT 06611	Monday – Friday 8:30am – 5:00pm	1480 scans in 2013
1.5 T Fixed, Closed	COS patients		Connecticut Orthopaedic Specialists 2416 Whitney Avenue, Hamden, CT 06518	Monday – Friday 7:30am – 8:15 pm Saturday 7:30am – 4:30 m Sunday by appointment	3773 scans in 2015
1.5T Fixed, Closed	COS patients		Connecticut Orthopaedic Specialists 84 North Main Street Branford, CT 06405	Monday – Friday 6:45 am – 8:00pm Saturday 7:00am – 5:00 pm	3851 scans in 2015
1.5T Mobile, Closed	Not publically available	Not publically available	Southern Connecticut Imaging Center LLC d/b/a Whitney Imaging Center 2200Whitney Avenue Hamden, CT 06518	Friday 7:30am – 4:30 pm	88 scans in 2013
1.5T Fixed, Open	Not publically available	Not publically available	Meriden Imaging Center, Inc. d/b/s Wallingford Diagnostic Imaging Center 863 North Main Street Wallingford, CT 06492	Monday – Friday 8:00am – 5:00pm	3276 scans in 2013
0.3T Fixed, Open	Not publically available	Not publically available	Diagnostic Imaging Services of CT, LLC d/b/a Branford Open MRI 1208 Main Street Branford, CT 06405	Monday, Tuesday, Thursday, Friday 8:00am - 5:00pm Wednesday 8:00am – 8:00pm	924 scans in 2013

000047

ESSEX, CT

Service or Program Name	Population Served	Facility ID*	Facility's Provider Name, Street Address and Town	Hours/Days of Operation	Current Utilization
1.5T Mobile, Closed	Not publically available	Not publically available	Middlesex Hospital d/b/a Shoreline Medical Center, ED 250 Flat Rock Place Westbrook, CT 06498	Tuesday, Thursday – Saturday 7:00am – 5:30pm	2,546 in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Yale-New Haven Hospital, Inc. Shoreline Medical Center 111 Goose Lane Guilford, CT 06437	Sunday – Saturday 24 hours	4,260 in 2013
1.5T Fixed, Closed	Not publically available	Not publically available	Guilford Radiology 1591 Boston Post Road Guilford, CT 06437	Monday – Friday 8:30am – 5:00pm	833 in 2013

* Provide the Medicare, Connecticut Department of Social Services (DSS), or National Provider Identifier (NPI) facility identifier and label column with the identifier used.

Source: *Statewide Health Care Facilities and Services Inventory – 2014. Table 8 (data from calendar year 2013).*

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Supplemental CON Application Form
Acquisition of Equipment
Conn. Gen. Stat. § 19a-638(a)(10),(11)

Applicant: **Connecticut Orthopaedic Specialists, P.C.**

Project Name: **Acquisition of a 1.5T Mobile MRI by a
Private Physician Practice**

000049

Affidavit

Applicant: Connecticut Orthopaedic Specialists, P.C.

Project Title: Acquisition of a 1.5 T Mobile MRI by a Private Physician Practice

I, Glenn F. Elia, CEO

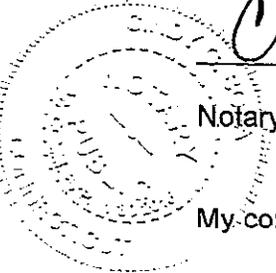
of Connecticut Orthopaedic Specialists, P.C., being duly sworn, depose and state that the said facility complies with the appropriate and applicable criteria as set forth in the Sections 19a-630, 19a-637, 19a-638, 19a-639, 19a-486 and/or 4-181 of the Connecticut General Statutes.


Signature _____ Date 7-19-16.

Subscribed and sworn to before me on July 19, 2016


Notary Public/Commissioner of Superior Court

My commission expires: Nov. 30, 2016


CINDY G. BOVA
NOTARY PUBLIC
MY COMMISSION EXPIRES
NOV. 30, 2016

1. Project Description: Acquisition of Equipment

- a. Provide the manufacturer, model and number of slices/tesla strength of the proposed scanner (as appropriate to each piece of equipment).

Response: The proposed mobile MRI scanner is a 2000 Mobile GE 1.5T scanner. The model is Excite (11X) 8 Channel MRI System.

- b. List each of the Applicant's sites and the imaging modalities currently offered by location.

Response: The two locations where COS currently offers MRI scanning are in Hamden and Branford. Each location has a fixed 1.5 Tesla MRI. X-Ray and fluoroscopy are also located in these two existing locations, but there are no other imaging modalities. The proposed mobile MRI scanner will be located at the COS office at 330 Boston Post Road, Orange, Connecticut on Monday and Tuesday. On Thursday and Friday it will be located at the COS office at 12 Bokum Road, Essex, Connecticut. MRI will be the only imaging modality offered at these locations.

2. Clear Public Need

- a. Complete Table A for each piece of equipment of the type proposed currently operated by the Applicant at each of the Applicant's sites.

TABLE A
EXISTING EQUIPMENT OPERATED BY THE APPLICANT

Provider Name/Address	Service*	Days/Hours of Operation **	Utilization***
Connecticut Orthopaedic Specialists, P.C. 84 North Main Street Branford, CT 06405	1.5 fixed, closed MRI	Monday – Friday, 7:00 am-8:00 pm Saturday - 7:00 am – 5:00 pm	3851 in 2015
Connecticut Orthopaedic Specialists, P.C. 2416 Whitney Avenue Hamden, CT 06518	1.5 fixed closed MRI	Monday – Friday, 7:00am-8:00pm Saturday, 7:00am – 5:00pm Sunday: By appointment	3773 in 2015

*Include equipment strength (e.g. slices, tesla strength), whether the unit is open or closed (for MRI)

**Days of the week unit is operational, and start and end time for each day

***Number of scans/exams performed on each unit for the most recent 12-month period (identify period).

- b. Provide the rationale for locating the proposed equipment at the proposed site;

Response:

Essex was selected as one of the two locations to offer MRI service two days a week because of the influx of new patients in the shoreline area with the addition of Shoreline Orthopedics & Sports Medicine (“Shoreline”) to COS. Shoreline has offices in Essex, Madison and Guilford. Orange was selected as the other site for the additional MRI service because of the volume of scanning at the Hamden and Branford offices and the accessibility it would offer to COS patients well within travel time to use the proposed Orange MRI depending upon where they live in relation to the service in Orange. These are COS patients currently using a COS MRI who will now transfer to the mobile MRI in Orange.

3. Actual and Projected Volume

- a. Complete the following tables for the past three fiscal years (“FY”), current fiscal year (“CFY”), and first three projected FYs of the proposal, for each of the Applicant’s existing and proposed pieces of equipment (of the type proposed, at the proposed location only). In **Table B**, report the units of service by piece of equipment, and in **Table C**, report the units of service by type of exam (e.g. if specializing in orthopedic, neurosurgery, or if there are scans that can be performed on the proposed scanner that the Applicant is unable to perform on its existing scanners).

TABLE B
HISTORICAL, CURRENT, AND PROJECTED VOLUME, BY EQUIPMENT UNIT

Equipment***	Actual Volume (Last 3 Completed FYs)			CFY Volume*	Projected Volume (First 3 Full Operational FYs)		
	FY 2013	FY 2014	FY 2015		FY 2016	FY 2017	FY 2018
Branford MRI	2,095	2,577	3,851	4,786 (annualized)	3,757	3,870	3,986
Hamden MRI	3,141	3,725	3,773	4,428 (annualized)	3,757	3,870	3,986
Orange MRI					1,500	1,545	1,591
Essex MRI					1,531	1,577	1,624
Total	5,236	6,302	7,624	9,214	10,545	10,862	11,187

*Annualized based on the first 6 months of FY 2016 (January to June). For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered.

Note: Applicant’s FY is a calendar year

TABLE C
HISTORICAL, CURRENT, AND PROJECTED VOLUME, BY TYPE OF SCAN/EXAM

Service***	Actual Volume (Last 3 Completed FYs)			CFY Volume*	Projected Volume (First 3 Full Operational FYs)		
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Orthopedic MRI scans	5,234	6,302	7,624	9,214	10,545	10,862	11,187
Total	5,264	6,302	7,624	9,214	10,545	10,862	11,187

*Annualized based on the first 6 months of FY 2016 (January to June). For periods greater than 6 months, report annualized volume, identifying the number of actual months covered and the method of annualizing. For periods less than six months, report actual volume and identify the period covered.

Note: Applicant's FY is a calendar year

- b. Provide a detailed explanation of all assumptions used in the derivation/ calculation of the projected volume by scanner and scan type.

Overall Assumptions

- A MRI scan takes 45 minutes.
- The optimum use rate for each scanner is 85% of the maximum number of scans possible within the scheduled hours of operation. This allows the scheduling for maintenance, downtime, cancellations and holidays, etc.
- The MRI scanners located in Hamden and Branford will operate 64 hours per week (Monday – Friday for 12 hours per day and 4 hours on Saturday) for a maximum of 85 scans per week or 4,420 scans per year. At an 85% use rate, the number of scans for each scanner on an annual basis is 3,757 scans. (This represents a reduction in hours of operation and number of scans currently performed at these locations).
- The reduction in the volume at Hamden and Branford will bring these scanners back to a normal, maximum use rate, and the overflow of patients is expected to utilize the mobile units in Orange and Essex.
- Initially, the mobile MRI scanner will operate 2 days per week in Orange and 2 days per week in Essex. The scanner will operate 12 hours per day at each location (a maximum of 32 scans per week or 1664 scans per year at each location). At an 85% use rate, the number of scans at each location in 2017 is 1414 (1664 scans x 85%).
- The annual rate of increase in MRI volume at each of the four locations for 2018 to 2019 is 3%. This is based on the historic rate of increase experienced

by the Applicant prior to the mergers of physician practices. Between 2012 and 2013, the rate of increase was 2.7%. See OHCA Table 5.

- In 2019 a third day of scanning can be added, if necessary, to either the Essex office or the Orange office depending upon which location has the largest volume of MRI scanning.

Essex Mobile MRI Assumptions

- The 2015 volume of COS patients from the Essex service area who received a MRI scan serves as the base for the projected utilization. Of the total 1,519 COS patients who received a MRI scan, 950 COS patients received a MRI at a COS MRI scanner and 569 were referred to a non-COS MRI. (Please see Table 8b, "Utilization by Town" and Exhibit J(1), p. 3 & Exhibit K).
- An annual rate of increase in volume of 3% was applied to the 2015 MRI volume for 2016 and 2017.
- It is assumed that approximately 5% of the patients will utilize either the Branford or Hamden MRI as they have in the past.

Orange Mobile MRI Assumptions

- An analysis of COS internal records for 2015 for 6 COS offices in Orange, Shelton and Milford was undertaken. Three of these are original COS offices (Orange, Shelton and Milford) and three are from the merger (one in Orange and two in Milford). It is assumed that the persons most likely to use the Orange MRI are residents of these towns or patients who use the COS offices in these towns.
- Based on the review of COS internal records for 2015, it is estimated that 9,555 new patients were seen at these offices and 15.6% required a MRI study (1,488 patients). Of these patients, 1,047 were accommodated at the COS Branford or Hamden MRI scanner and 447 were referred to a non-COS MRI. These 1,488 COS patients serve as the base for the projected utilization. See Table #8a and Exhibit L in the Main Application.
- An annual rate of increase in volume of 3% was applied to the 2015 MRI volume for 2016 and 2017.
- It is assumed that approximately 5% of the 1,488 COS patients will utilize either the Branford or Hamden MRI as they have in the past

- c. Explain any increases and/or decreases in the volume reported in the tables above.

Response:

COS has experienced significant increases in utilization from 2013 to 2016. This increase exists on both the Hamden and Branford existing 1.5 T fixed MRIs that are now over-capacity. The increase is projected to continue through 2016. The increases in utilization are as follows:

2013 - 2014	20.4% increase
2014 - 2015	21% increase
2015 - 2016	21% increase (projected)

The increases that occurred between 2013 and 2016 (through June) are due to two factors, the merger of four existing orthopedic physician practices into COS, and an increase in the hours of operation. (Please see response to Question #1 in the Main Application for more detail on the mergers, the impact on volume, and extended hours of hours of operation). The rate of increase is anticipated to slow in 2017 due to the “maturation” of the merger (with the exception of the patients from the Shoreline Orthopedics & Sports Medicine who are still being referred to other providers).

- d. Provide a breakdown, by town, of the volumes provided in **Table C** for the most recently completed FY.

**TABLE D1
COS ORANGE
UTILIZATION BY COS SCANNER BY SERVICE AREA TOWN**

Town	Hamden COS MRI FY 2015	Branford COS MRI FY 2015	Total COS MRI FY 2015*
Orange	150	82	232
New Haven	357	269	626
West Haven	238	279	517
Milford	240	263	503
Woodbridge	112	46	158
Shelton	39	17	56
Derby	29	6	35
North Haven	291	125	416
East Haven	60	390	450
Stratford	42	14	56
Total Service Area Towns	1,558	1,491	3,049

*Number of patients from the primary service area receiving MRI scans performed on Hamden or Branford COS MRI scanner in FY2015

See **Exhibit J(2) & J(3) in the Main Application for a total MRIs by patient town for 2015 for each of the Hamden and Branford COS MRI scanners.

**TABLE D2
ESSEX
UTILIZATION BY COS SCANNER BY SERVICE AREA TOWN**

Town	Hamden COS MRI FY 2015*	Branford COS MRI FY 2015**	Total COS MRI FY 2015
Essex	2	10	12
Madison	23	276	299
Clinton	7	114	121
Old Saybrook	3	36	39
Westbrook	5	28	33
Old Lyme	3	25	28
Deep River	0	12	12
Chester	1	7	8
Guilford	29	369	398
Total Service Area Towns	73	877	950

*Number of patients from primary service area receiving MRI scans performed on Hamden or Branford COS MRI scanner

See **Exhibit J(2) & J(3) in the Main Application for the total MRIs by patient town for 2015 for each of the Hamden and Branford COS MRI scanners.

The Applicant proposes to add one 1.5 Tesla mobile scanner which will be utilized in an orthopedic physicians' office (outpatient). It will move between Orange for 2 days per week and Essex for two days per week. Both existing MRI scanners are fixed, 1.5 T, closed units.

Exhibit List

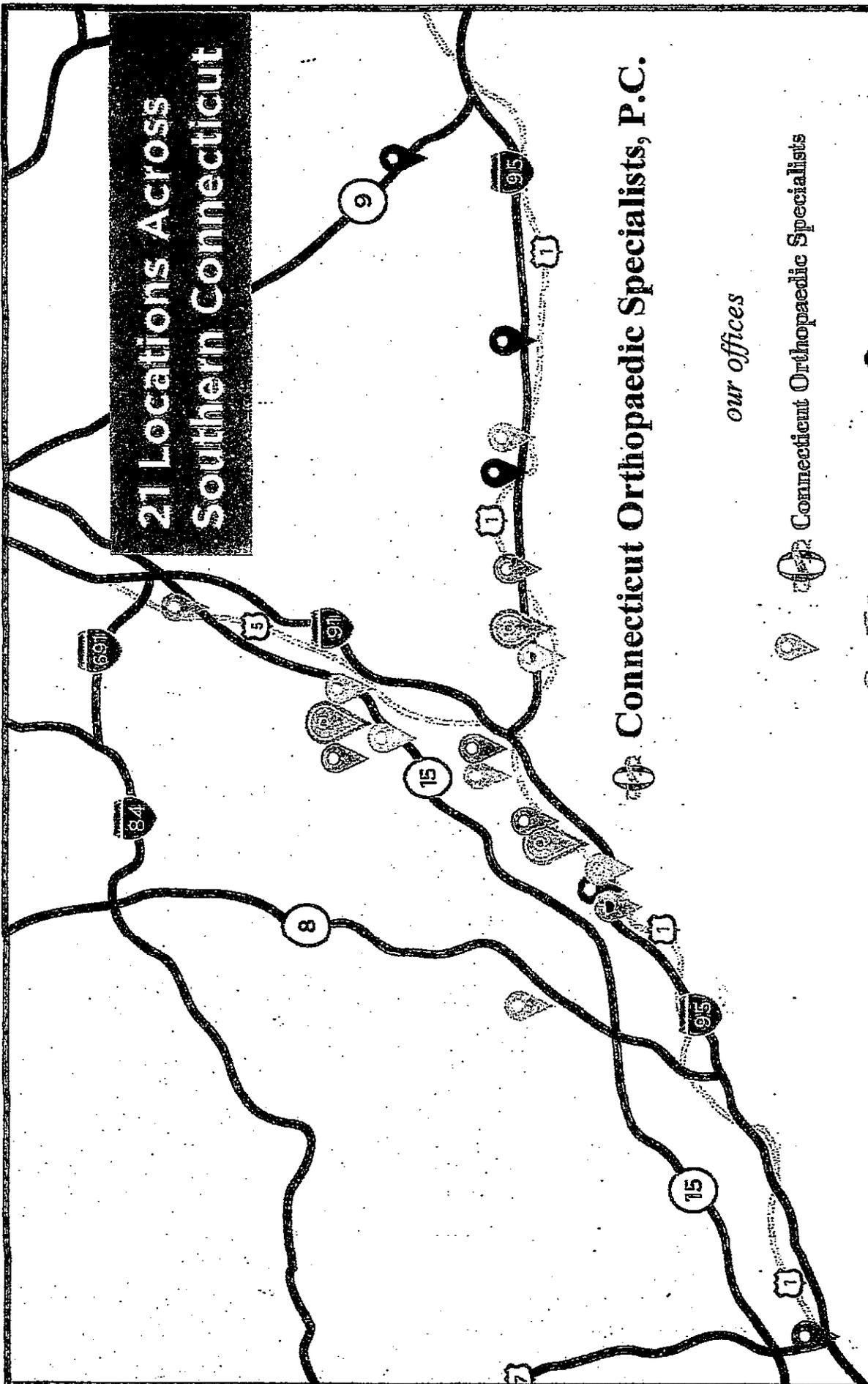
Exhibit	Description	Pages
A	Map of COS Locations; List of COS Office Addresses; and List of All COS Physicians.	59 - 68
B	Graphs of Increased MRI Scanning in Hamden and Branford FY 2013 - 2016.	69 - 72
C	DPH License for Outpatient Surgery Center in Branford.	73 - 74
D	List of Key Professional, Administrative, Clinical and Direct Service Personnel and Curriculum Vitae	75 - 91
E	Scholarly Articles	92 - 122
F	Letters of Support	123 - 130
G	COS Standard of Practice Guidelines	131 - 171
H	American College of Radiology Accreditation for Existing MRI Scanners	172 - 174
I	COS Charity Care Policy	175 - 176
J	Target Populations: Patient Zip Codes	177 - 193
K	FY2015MRI Scans in the Essex Area for COS Patients	194 - 196
L	FY2015MRI Scans in the Orange Area for COS Patients	197 - 198
M	Capital Expenditures for Mobile MRI and Quotation for Trailer Installations	199 - 203
N	Funding or Financial Resources for the Project	204 - 208

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O	COS Financial Statements; Balance Sheets and Related Income Statements for FY 2014 and 2015	209 - 213
P	Financial Worksheet	214 - 215
Q	Assumptions Used in Financial Worksheet	216 - 218

EXHIBIT A

**21 Locations Across
Southern Connecticut**



Connecticut Orthopaedic Specialists, P.C.

our offices

- Connecticut Orthopaedic Specialists
- The Orthopaedic Group
- Orthopaedic Health
- SHORELINE ORTHOPEDICS & SPORTS MEDICINE
- Center for Orthopaedics



Connecticut Orthopaedic Specialists

AND OUR DIVISIONS

The Orthopaedic Group

Orthopedic Health



Center For Orthopaedics

SHORELINE

ORTHOPEDICS & SPORTS MEDICINE

Office address	address 2	city	state	zip	phone
1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
469 West Main Street		Branford	CT	06405	203.865.6784
84 North Main Street		Branford	CT	06405	203.407.3516
12 Bokum Road		Essex	CT	06426	860.767.9053
450 Boston Post Road		Guilford	CT	06437	203.407.3505
47 Clapboard Hill Road	Suite 4	Guilford	CT	06437	203.433.0906
2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
2408 Whitney		Hamden	CT	06518	203.407.3505
9 Washington Avenue		Hamden	CT	06518	203.865.6784
1353 Boston Post Road		Madison	CT	06443	203.245.7447
6 Woodland Road	Suite 3B	Madison	CT	06443	203.433.0906
258 South Broad Street		Milford	CT	06460	203.867.6448
30 Commerce Park		Milford	CT	06460	203.865.6784
849 Boston Post Road	Suite 101	Milford	CT	06460	203.877.5522
230 George Street	5th Floor	New Haven	CT	06510	203.752.3100
330 Orchard Street		New Haven	CT	06511	203.407.3516
148 East Avenue	Suite 2E	Norwalk	CT	06851	203.853.2967
330 Boston Post Road		Orange	CT	06477	203.407.3505
464 Boston Post Road		Orange	CT	06477	203.752.3100
889 Bridgeport Avenue		Shelton	CT	06484	203.407.3516
1000 Yale Avenue		Wallingford	CT	06492	203.407.3505

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The Connecticut Orthopaedic Specialists

AND OUR DIVISIONS


The Orthopaedic Group Orthopaedic Health

Center For Orthopaedics

SHORELINE ORTHOPEDICS & SPORTS MEDICINE

Listed by Office of Origin:

Physicians	Office address	address 2	city	state	zip	phone
Connecticut Orthopaedic Specialists P.C.						
John M. Aversa, MD	450 Boston Post Road		Guilford	CT	06437	203.407.3505
	2408 Whitney		Hamden	CT	06518	203.407.3505
	330 Boston Post Road		Orange	CT	06477	203.407.3505
John M. Beiner, MD	1000 Yale Avenue		Wallingford	CT	06492	203.407.3505
	2408 Whitney		Hamden	CT	06518	203.407.3516
	84 North Main Street		Branford	CT	06405	203.407.3516
	450 Boston Post Road		Guilford	CT	06437	203.407.3516
	330 Orchard Street		New Haven	CT	06511	203.407.3516
Hubert B. Bradburn, MD	889 Bridgeport Avenue		Shelton	CT	06484	203.407.3516
	1000 Yale Avenue		Wallingford	CT	06492	203.407.3516
	450 Boston Post Road		Guilford	CT	06437	203.407.3510
	2408 Whitney		Hamden	CT	06518	203.407.3518
	330 Boston Post Road		Orange	CT	06477	203.407.3518
David B. Cohen, MD	84 North Main Street		Branford	CT	06405	203.407.3518
	1000 Yale Avenue		Wallingford	CT	06492	203.407.3518
	84 North Main Street		Branford	CT	06405	203.867.6448
	1000 Yale Avenue		Wallingford	CT	06492	203.867.6448
	889 Bridgeport Avenue		Shelton	CT	06484	203.867.6448
Peter A. Deluca, MD	258 South Broad Street		Milford	CT	06460	203.867.6448
	2408 Whitney		Hamden	CT	06518	203.407.3540
	84 North Main Street		Branford	CT	06405	203.407.3540
	1000 Yale Avenue		Wallingford	CT	06492	203.407.3540
	330 Boston Post Road		Orange	CT	06477	203.407.3540
Richard Diana, MD						

Physicians	Office address	address 2	city	state	zip	phone
Allen M. Ferrucci, MD	2408 Whitney		Hamden	CT	06518	203.407.3525
	450 Boston Post Road		Guilford	CT	06437	203.407.3525
	84 North Main Street		Branford	CT	06405	203.407.3525
	1000 Yale Avenue		Wallingford	CT	06492	203.407.3525
Norman R. Kaplan, MD	330 Boston Post Road		Orange	CT	06477	203.407.3525
	258 South Broad Street		Milford	CT	06460	203.407.3520
	330 Boston Post Road		Orange	CT	06477	203.407.3520
	2408 Whitney		Hamden	CT	06518	203.407.3520
John D. Kelley, MD	1000 Yale Avenue		Wallingford	CT	06492	203.407.3520
	450 Boston Post Road		Guilford	CT	06437	203.407.3520
	450 Boston Post Road		Guilford	CT	06437	203.407.3535
	330 Boston Post Road		Orange	CT	06477	203.407.3535
Jeffrey M. Klauser, MD Kenneth M. Kramer, MD	84 North Main Street		Branford	CT	06405	203.407.3535
	2408 Whitney		Hamden	CT	06518	203.407.3535
	889 Bridgeport Avenue		Shelton	CT	06484	203.538.0022
	2408 Whitney		Hamden	CT	06518	203.407.3530
John D. McCallum, MD	330 Boston Post Road		Orange	CT	06477	203.407.3530
	450 Boston Post Road		Guilford	CT	06437	203.407.3530
	84 North Main Street		Branford	CT	06405	203.407.3530
	1000 Yale Avenue		Wallingford	CT	06492	203.407.3530
Philip A. Minotti, MD	84 North Main Street		Branford	CT	06405	203.407.3545
	258 South Broad Street		Milford	CT	06460	203.407.3545
	2408 Whitney		Hamden	CT	06518	203.407.3545
	450 Boston Post Road		Guilford	CT	06437	203.407.3545
Thomas P. Moran, MD	889 Bridgeport Avenue		Shelton	CT	06484	203.407.3544
	330 Orchard Street		New Haven	CT	06511	203.407.3544
	2408 Whitney		Hamden	CT	06518	203.407.3544
	84 North Main Street		Branford	CT	06405	203.407.3544
Thomas P. Moran, MD	330 Boston Post Road		Orange	CT	06477	203.407.3544
	450 Boston Post Road		Guilford	CT	06437	203.407.3510
	84 North Main Street		Branford	CT	06405	203.407.3510
	2408 Whitney		Hamden	CT	06518	203.407.3510
	258 South Broad Street		Milford	CT	06460	203.407.3510

John D. McCallum, MD	450 Boston Post Road	Guilford	06437	203.407.3530
	84 North Main Street	Branford	06405	203.407.3530
	1000 Yale Avenue	Wallingford	06492	203.407.3530
	84 North Main Street	Branford	06405	203.407.3545
	258 South Broad Street	Milford	06460	203.407.3545
	2408 Whitney	Hamden	06518	203.407.3545
	450 Boston Post Road	Guilford	06437	203.407.3545
Philip A. Minotti, MD	889 Bridgeport Avenue	Shelton	06484	203.407.3544
	330 Orchard Street	New Haven	06511	203.407.3544
	2408 Whitney	Hamden	06518	203.407.3544
	84 North Main Street	Branford	06405	203.407.3544
	330 Boston Post Road	Orange	06477	203.407.3544
	450 Boston Post Road	Guilford	06437	203.407.3510
Thomas P. Moran, MD	84 North Main Street	Branford	06405	203.407.3510
	2408 Whitney	Hamden	06518	203.407.3510
	258 South Broad Street	Milford	06460	203.407.3510
	84 North Main Street	Branford	06405	203.407.3534
Patrick A. Ruwe, MD	258 South Broad Street	Milford	06460	203.407.3534
	450 Boston Post Road	Guilford	06437	203.407.3534
	330 Boston Post Road	Orange	06477	203.407.3534
	2408 Whitney	Hamden	06518	203.407.3534
	2408 Whitney	Hamden	06518	203.407.3539
Mark W. Scanian, MD	1000 Yale Avenue	Wallingford	06492	203.407.3539
	258 South Broad Street	Milford	06460	203.407.3539
	330 Boston Post Road	Orange	06477	203.407.3539
	84 North Main Street	Branford	06405	203.407.3539
	2408 Whitney	Hamden	06518	203.407.3568
Enzo J. Sella, MD	450 Boston Post Road	Guilford	06437	203.407.3568
	330 Boston Post Road	Orange	06477	203.407.3568
	2408 Whitney	Hamden	06518	203.407.3585
Sanda L. Tomak, MD	330 Orchard Street	New Haven	06511	203.407.3585
	330 Boston Post Road	Orange	06477	203.407.3585
	450 Boston Post Road	Guilford	06437	203.407.3585
	84 North Main Street	Branford	06405	203.407.3585
	2408 Whitney	Hamden	06518	203.407.3528
David S. Caminear, DPM	450 Boston Post Road	Guilford	06437	203.407.3528

Jeffrey M. DeLott, DPM	1000 Yale Avenue	Wallingford	CT	06492	203.407.3528
	330 Boston Post Road	Orange	CT	06477	203.407.3528
	258 South Broad Street	Milford	CT	06460	203.407.3586
	84 North Main Street	Branford	CT	06405	203.407.3586
	2408 Whitney	Hamden	CT	06518	203.407.3586
	889 Bridgeport Avenue	Shelton	CT	06484	203.407.3586
	330 Orchard Street	New Haven	CT	06511	203.407.3586
John Marino, MD	330 Boston Post Road	Orange	CT	06477	203.407.3589
	84 North Main Street	Branford	CT	06405	203.407.3589
	258 South Broad Street	Milford	CT	06460	203.407.3589
	1000 Yale Avenue	Wallingford	CT	06492	203.407.3589
Rakesh Patel, MD	1000 Yale Avenue	Wallingford	CT	06492	203.407.3574
	258 South Broad Street	Milford	CT	06460	203.407.3574
	2408 Whitney	Hamden	CT	06518	203.407.3574
	889 Bridgeport Avenue	Shelton	CT	06484	203.407.3574
Jonas Lieponis, MD	258 Broad Street	Milford	CT	06460	203.433.0906
	6 Woodland Road	Madison	CT	06443	203.433.0906
	47 Clapboard Hill Road	Guilford	CT	06437	203.433.0906
(administrative only)	6 Woodland Road	Madison	CT	06443	203.453.2780
Michael J. Murphy, MD	258 Broad Street	Milford	CT	06460	203.453.2780
(administrative only)	47 Clapboard Hill Road	Guilford	CT	06437	203.453.2780

Physicians	Office address	address 2	city	state	zip	phone
Orthopedic Health						
Tedd L. Weisman, MD	849 Boston Post Road	Suite 101	Milford	CT	06460	203.877.5522
Amit Lahav, MD	849 Boston Post Road	Suite 101	Milford	CT	06460	203.877.5522
Aaron Schachter, MD	849 Boston Post Road	Suite 101	Milford	CT	06460	203.877.5522
Center for Orthopaedics						
Oluwaseun Akinbo, MD	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
Mark P. Altman, MD	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
	148 East Avenue	Suite 2E	Norwalk	CT	06851	203.853.2967
Stephanie Arlis-Mayor, MD	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
John Daigneault, MD	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
David H. Gibson, MD	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	230 George Street	5th Floor	New Haven	CT	06510	203.752.3100
Rowland B. Mayor, MD	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
Durgadas P. Sakalkale, MD	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
Jeffrey M. Sumner, MD	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100
Joseph C. Wu, MD	1224 Main Street	Lockworks Square	Branford	CT	06405	203.752.3100
	2200 Whitney Avenue	Suite 170	Hamden	CT	06518	203.752.3100
	464 Boston Post Road		Orange	CT	06477	203.752.3100

The Orthopaedic Group

Richard A. Bernstein, MD

9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
30 Commerce Park	Milford	CT	06460	203.865.6784
9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
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9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
30 Commerce Park	Milford	CT	06460	203.865.6784
9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
30 Commerce Park	Milford	CT	06460	203.865.6784

John F. Irving, MD

Christopher B. Lynch, MD

Alan M. Reznik, MD

Derek S. Shia, MD

Shirvinda A. Wijesekera, MD

Richard A. Zell, MD

Adriana Blanco, MD

Shoreline Orthopedics and Sports Medicine

Mark D. Lorenze, MD

Steven M. Luster, MD

Martin J. White, MD

Connecticut Orthopaedic Specialists

John M. Aversa, MD

12 Bokum Road	Essex	CT	06426	860.767.9053
1353 Boston Post Road	Madison	CT	06443	203.245.7447
12 Bokum Road	Essex	CT	06426	860.767.9053
1353 Boston Post Road	Madison	CT	06443	203.245.7447
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330 Boston Post Road	Orange	CT	06477	203.407.3505
1000 Yale Avenue	Wallingford	CT	06492	203.407.3505
2408 Whitney	Hamden	CT	06518	203.407.3505
450 Boston Post Road	Guilford	CT	06437	203.407.3505

The Orthopaedic Group

Richard A. Bernstein, MD

9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
30 Commerce Park	Milford	CT	06460	203.865.6784
9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
30 Commerce Park	Milford	CT	06460	203.865.6784
9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
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9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
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469 West Main Street	Branford	CT	06405	203.865.6784
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9 Washington Avenue	Hamden	CT	06518	203.865.6784
469 West Main Street	Branford	CT	06405	203.865.6784
30 Commerce Park	Milford	CT	06460	203.865.6784

John F. Irving, MD

Christopher B. Lynch, MD

Alan M. Reznik, MD

Derek S. Shia, MD

Shirvinda A. Wijesekera, MD

Richard A. Zell, MD

Adriana Blanco, MD

Shoreline Orthopedics and Sports Medicine

Mark D. Lorenze, MD

Steven M. Luster, MD

Martin J. White, MD

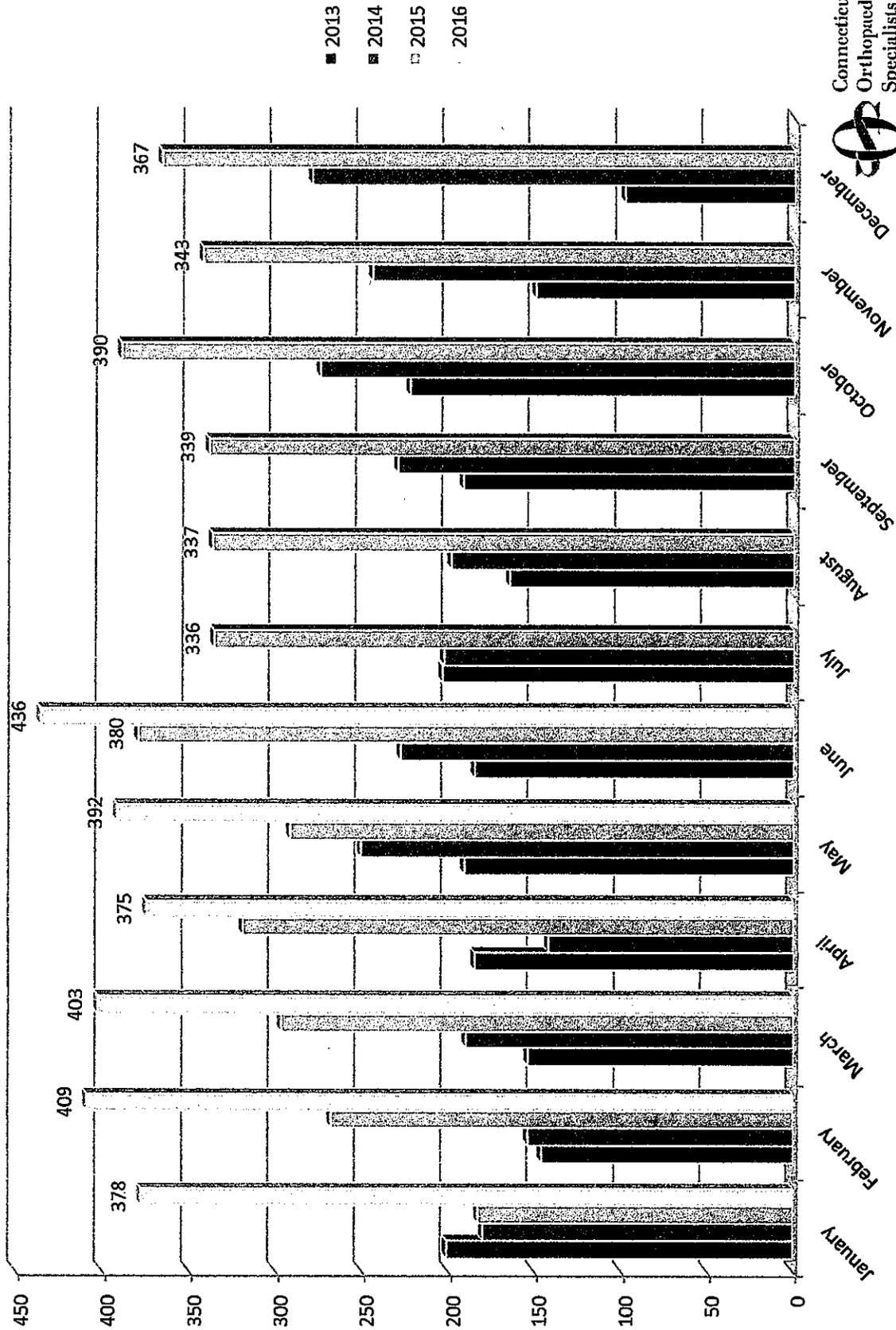
Connecticut Orthopaedic Specialists

John M. Aversa, MD

12 Bokum Road	Essex	CT	06426	860.767.9053
1353 Boston Post Road	Madison	CT	06443	203.245.7447
12 Bokum Road	Essex	CT	06426	860.767.9053
1353 Boston Post Road	Madison	CT	06443	203.245.7447
12 Bokum Road	Essex	CT	06426	860.767.9053
330 Boston Post Road	Orange	CT	06477	203.407.3505
1000 Yale Avenue	Wallingford	CT	06492	203.407.3505
2408 Whitney	Hamden	CT	06518	203.407.3505
450 Boston Post Road	Guilford	CT	06437	203.407.3505

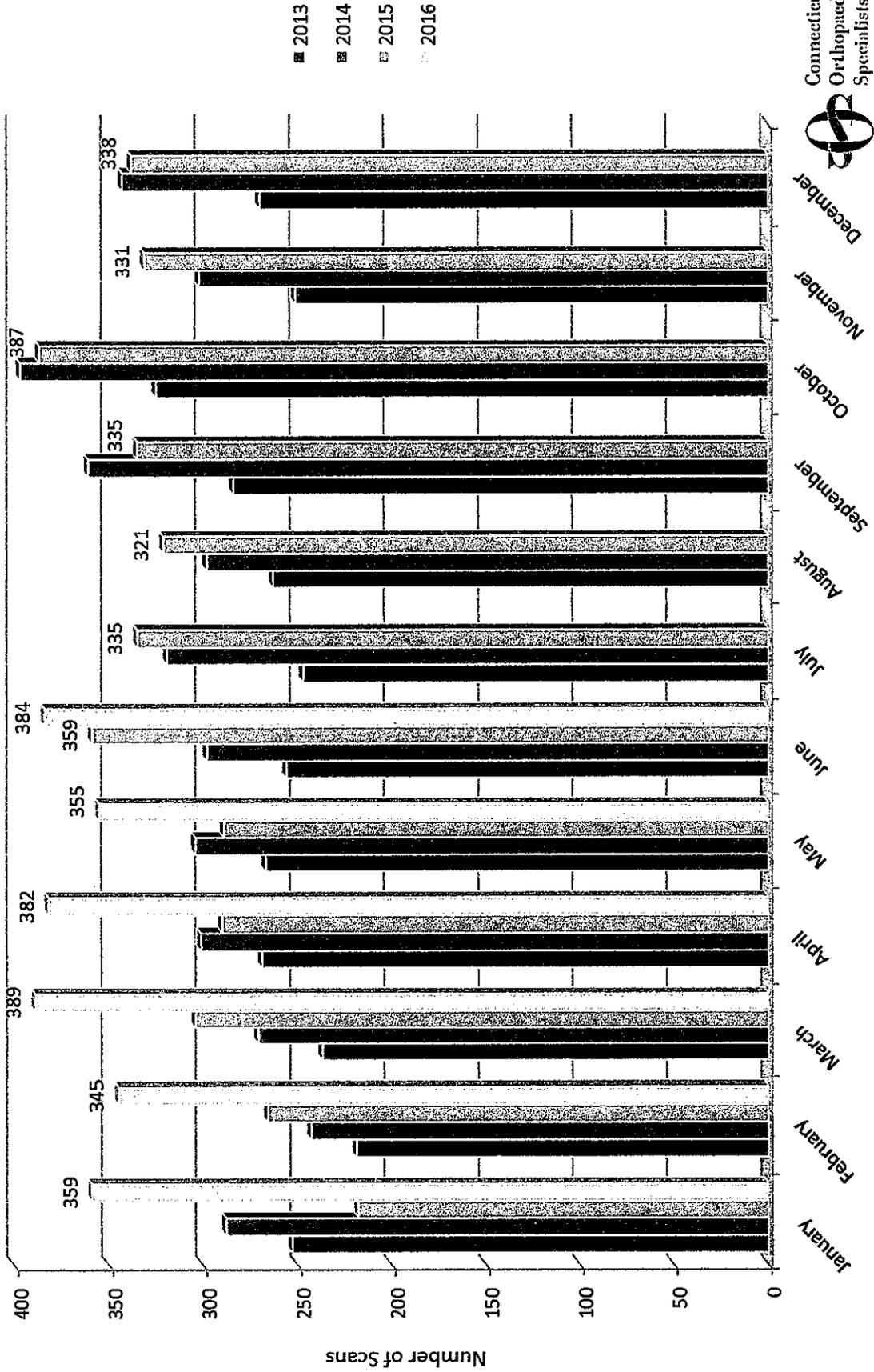
EXHIBIT B

Connecticut Orthopaedic Specialists Branford MRI Facility Number of Scans 2013 through June of 2016



010070

Connecticut Orthopaedic Specialists Hamden MRI Facility Number of Scans 2013 through June of 2016



120071

Connecticut Orthopaedic Specialists

The Orthopaedic Group Orthopaedic Health  Center For Orthopaedics  SHORELINE ORTHOPEDICS & SF

2013 -2016 Connecticut Orthopaedic Specialists Monthly MRI Data by Scanner

	January	February	March	April	May	June	July	August	September	October	November	December	Total
Branford													
2013	201	146	154	185	191	185	204	165	192	223	150	99	2,095
2014	180	154	190	142	251	228	203	199	230	275	245	280	2,577
2015	183	268	297	319	292	380	336	337	339	390	343	367	3,851
2016	378	409	403	375	392	436							

	January	February	March	April	May	June	July	August	September	October	November	December	Total
Hamden													
2013	253	219	237	269	267	256	247	263	284	325	251	270	3,141
2014	288	243	271	301	304	298	319	298	361	397	302	343	3,725
2015	218	266	304	290	289	359	335	321	335	387	331	338	3,773
2016	359	345	389	382	355	384							

EXHIBIT C

000073

STATE OF CONNECTICUT

Department of Public Health

LICENSE

License No. 0339

Out-Patient Surgical Facility

In accordance with the provisions of the General Statutes of Connecticut Section 19a-493:

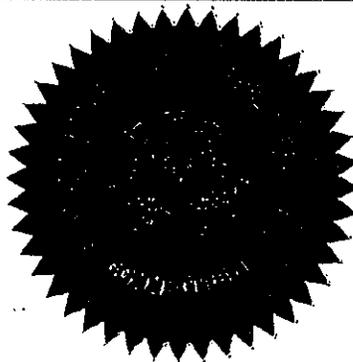
Connecticut Orthopaedic Specialists Outpatient Surgical Center, LLC of Branford, CT, d/b/a is hereby licensed to maintain and operate an Out-Patient Surgical Facility.

Connecticut Orthopaedic Specialist Outpatient Surgical Center, LLC is located at 84 North Main Street, Building 2, 1st. Floor, Branford, CT 06405.

This license expires **December 31, 2017** and may be revoked for cause at any time.

Dated at Hartford, Connecticut, January 1, 2016. **RENEWAL**

Waiver Section 19-13-D56(e)(8)(B) exp: n/a eff: 1-13-16



Raul Pino

Raul Pino, MD, MPH
Acting Commissioner

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EXHIBIT D

000075

List of all Key Professional, Administrative, Clinical and Direct Service Personnel
Related to the Proposal:

1. Anthony Gagliardi, M.D.; Radiologist
2. Joanne E. Elderidge; MRI Senior Tech/Supervisor for COS, and MRI Tech
(Branford)
3. Billie Jo Foraker; Clinical Office Manager and Radiology Manager – COS
Division
4. Carlene Fox; RT, (R) (MR); MRI Technologist
5. Glenn F. Elia, M.B.A., R.P.T.; CEO of CT Orthopaedic Specialists, P.C.

CURRICULUM VITAE

PERSONAL DATA:

Joseph Anthony Gagliardi
DOB: May 20, 1959
Place: New Haven, CT
Citizenship: USA

EDUCATION:

Yale University, BS, Psychobiology, 1978-82
New York Medical College, Valhalla, NY, M.D., Medicine, 1982-86

TRAINEESHIP:

Internship: St. Vincent's Medical Center, Bridgeport, CT, Transitional, 1986-87
Residency: St. Vincent's Medical Center, Bridgeport, CT, Diagnostic Radiology, 1987-91
Chief Resident, 1990-1991

LICENSURE:

Connecticut #029458, 1988
Hawaii #7589, 1991-1995
DEA #BG2862374, 1989

MILITARY SERVICE:

Active Duty US Army M.C., Tripler A.M.C., Honolulu, HI, 1991-1995

MEMBERSHIP IN PROFESSIONAL SOCIETIES:

Radiological Society of North America
Hawaii Radiologic Society 1991-1995
American Roentgen Ray Society
Connecticut Radiologic Society 1995-2010
Association of Program Directors in Radiology 2004-2010

ACADEMIC APPOINTMENTS:

Associate Clinical Professor, Department of Radiology, University of Hawaii, Manoa, 1992-1997
Assistant Clinical Professor, Department of Radiology, New York Presbyterian Healthcare, 1999-present
Clinical Adjunct Associate Professor, Quinnipiac University School of Health Sciences, 2004-present
Assistant Clinical Professor, Department of Diagnostic Radiology, Yale School of Medicine, 2010-present

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HOSPITAL APPOINTMENTS:

Chief, Musculoskeletal Radiology, Tripler Army Medical Center, Honolulu, HI, 1991-1992

Chief, Genitourinary Radiology, Tripler Army Medical Center, Honolulu, HI, 1992-1995

Academic Council/Surgical Case Review, Tripler Army Medical Center, Honolulu, HI, 1992-1995

Chief, Musculoskeletal Radiology, St. Vincent's Medical Center, Bridgeport, CT, 1995-2009

Residency Program Co-Director, St. Vincent's Medical Center, Bridgeport, CT, 1999-2003

Vice Chairperson, Department of Radiology, St. Vincent's Medical Center, Bridgeport, CT, 2001-2005

Residency Program Director, St. Vincent's Medical Center, Bridgeport, CT, 2003-2009

Chairperson, Department of Radiology, St. Vincent's Medical Center, Bridgeport, CT, 2006-2009

Veterans Administration Medical System, West Haven, CT, 2010-present

REGULAR TEACHING ACTIVITIES:

St. Vincent's Medical Center, Diagnostic Radiology Conference: Present lectures and cases for resident and staff teaching. Invited audience consists of Radiology staff and residents.

Yale University Medical Center, Diagnostic Radiology Conference: Present lectures and cases for resident and staff teaching. Invited audience consists of Radiology staff and residents.

PROFESSIONAL ACTIVITIES:

Manuscript Reviewer, Consultant Magazine, Cligott Publishing Co., 55 Holly Hill Lane, Greenwich, CT 06831, 1998-present.

FDA Investigational New Drug Number 48,354 issued for Magnetic Resonance Imaging research of musculoskeletal disorders following intra-articular administration of Gadolinium.

American Board of Radiology, Board Examiner, Musculoskeletal Section, 1999-present.

Board Member, Musculoskeletal Section, Mediaworks, Inc. Electronic journal: *Radiology web.Com*. 1999-present.

Professional Liability Committee member, St. Vincent's Medical Center. 2001-2009.

Medical Executive Committee Member, St. Vincent's Medical Center, 2004-2009.

American Board of Radiology Item Writing Task Force for Written Board Exam, 2005-present.

American College of Radiology, 2006-2010.

Manuscript Reviewer, Journal of Neuroimaging, Blackwell Publishing, 2008 – present.

PUBLICATIONS:

A. Original Articles

1. Gagliardi JA, Interventional Radiology Complication Rates. *Administrative Radiology* 1992; 11:90-99
2. Chandnani VP, Yeager TD, DeBerardino TM, Christensen K, Gagliardi, JA, Heitz DR, Baird DE, Hansen MF. Glenoid Labral Tears: Prospective Evaluation with MR Imaging, MR Arthrography and CT Arthrography. *AJR* 1993; 161:1229-1235
3. Chandnani VP, Harper MT, Ficke J, Gagliardi JA, Rolling L, Christensen K, Hansen MF. Chronic Ankle Instability. Evaluation with MR Arthrography, MR Imaging, and Stress Radiography. *Radiology* 1994; 192:189-94
4. Gagliardi, JA, Chung EM, Chandnani VP, Kesling KL, Christensen KP, Null RN, Radvany MG, Hansen MF. Detection and Staging of Chondromalacia Patella: Relative Efficacies of Conventional MR Imaging, MR Arthrography and Computed Arthrotomography. *AJR* 1994; 163: 629-636
5. Chandnani VP, Gagliardi JA, Murnane TG, Bradley YC, DeBerardino TM, Spaeth J, Hansen MF. Glenohumeral Ligaments and Shoulder Capsular Mechanism: Evaluation with MR Arthrography. *Radiology* 1995; 196:27-32
6. Bradley YC, Chandnani VP, Gagliardi JA, Reeves TQ. Partial Thickness Supraspinatus Tears; Diagnosis by Magnetic Resonance Arthrography. *Australas Radiol* 1995; 39(2): 124-127
7. Riccio GJ, Gagliardi JA. Pitfalls in Hysterosalpingographic Interpretation. *Postgraduate Radiology* 1997; 17:190-208
8. Gagliardi JA, Nunberg SM, Fisher T. Fracture Detection: A Possible Method to Aid in Diagnosis and Improve Reporting Accuracy. *Radiologyweb.com*. April Issue 2001

B. Case Reports

1. Gagliardi, JA, Chaddha, SKB. CNS Toxoplasmosis. *Consultant* 1991; 31: 45-48
2. Gagliardi JA, Torstenson G. Fibrous Dysplasia in the Skull Base. *Applied Radiology* 1991; 20: 42-43
3. Gagliardi JA, Chaddha SKB. Mid Gut Volvulus with Computed Tomography. *Applied Radiology* 1992; 21: 58-59
4. Gagliardi JA, Posch R. Flare Response in Nuclear Medicine Secondary to Chemotherapy Toxicity to the Kidneys. *Applied Radiology* 1992; 21:24-25
5. Gagliardi JA, Eline MJ. Minimal Plain Film Findings of a Femoral Neck Osteoid Osteoma Diagnosed by Radionuclide Bone Scintigraphy and MRI. *Clinical Nuclear Medicine* 1993; 18:446-447
6. Zaheer W, Friedland ML, Cooper EB, Dorosario A, Burd R, Gagliardi JA, Torstenson G. Spontaneous Regression of Small Cell Lung Cancer Associated with Severe Neuropathy. *Cancer Investigation* 1993; 11:306-309

7. Shanley DJ, Gagliardi JA, Daum-Kowalski R. Choledochal Cyst Complicating Pregnancy: Antepartum Diagnosis with MRI. *Abdom Imaging* 1994; 19: 61-62
8. Radvany MG, Shanley DJ, Gagliardi JA. Magnetic Resonance Imaging with Computed Tomography of a Renal Leiomyoma. *Abdom Imaging* 1994; 19:67-69
9. Quan SS, Gagliardi JA*, Russo RD. Neurofibromatosis. *Applied Radiology* 1994; 23: 35-26
10. Samlaska CP, Gagliardi JA. Diffuse Venous Malformation with Intraosseous Involvement. *Hawaii Medical Journal* 1994; 53: 218-221
11. Gagliardi JA, Evans EM, Chandnani VP, Myers JB, Pacheco CM. Osteogenesis Imperfecta Complicated by Osteosarcoma. *Skeletal Rad* 1995; 24(4): 308-310
12. Munter FM, Gagliardi JA, Russo RD. Familial Hyperphosphatasemia. *Applied Radiology* 1995; 25(7): 44-45
13. Eclavea A, Gagliardi JA, Jezior J, Burton B, Donahue J. Pheochromocytoma with Central Nervous System Manifestations. *Australasian Radiology* 1997 41(4): 373-376
14. Lustberg H, Gagliardi JA, Lawson JP. Digital Enlargement in Tuberous Sclerosis. *Skeletal Radiology* 1999; 28:116-118
15. Gagliardi JA. Musculoskeletal Involvement of Sarcoidosis in the Hands. Electronic Journal: *Radiologyweb .Com*. December Issue, 1999
16. Gagliardi JA. Silicone Implant Arthropathy of the Wrist. Electronic Journal: *Radiologyweb.Com*. September Issue, 2000
17. Gagliardi JA, Duff MK, Callahan T, Pannese JR. Abnormal Dilatation to the Internal Carotid Artery on Angiography without Abnormal Finding at Craniotomy: Connecticut Medicine 2004; 68:3-5
18. Hyo-Jeong Lee, Gagliardi JA. Diffuse pigmented villonodular synovitis. *Applied Radiology* 2004; 33(12):41-43
19. Udeshi M, Gagliardi JA. Foreign body giant cell reaction to polytetrafluoroethylene used as interposition material in scaphoid-trapezium arthroplasty. *Australasian Radiology* 2006; 50:233-236
20. Martinez F, Gagliardi JA, Olsavsky TD. Gastrointestinal stromal tumor originating in the stomach. *Applied Radiology* 2006; 35(7): 43-46.
21. Gripp M, Gagliardi JA. Calciphylaxis On Technetium Bone Scan: Two Case Reports. *Radiology Case Reports* 2007; 2(2):30-32.
22. Rastogi P, Gagliardi JA, Bharucha R. Manifestations of Von Hippel-Lindau disease. *Applied Radiology* 2007; 36(11):62-65.
23. Swain FR, Udeshi M, Gagliardi JA, Armm M. Fracture of the Penis: MR Imaging with Surgical Correlation. *Radiology Case Reports Epub* 2007; 2 (3).
24. Werder GM, Razdan RS, Gagliardi JA, Chaddha SKB. Conservatively managed pineal apoplexy in an anticoagulated patient. *Radiography* 2008; 14:69-72.
25. Tagg W, Woods S, Razdan R, Gagliardi J, Steenbergen P. Hemoperitoneum after Colonoscopy. Endoscopy. *Accepted for publication ID ENDOS -2008-1226.R1*

26. Martinez F., Cho Y., Gagliardi JA, Razdan R. Spontaneous Pneumomediastinum. *Applied Radiology* 2008;37(4):40-44.
27. Werder GM, Tangri RK, Gagliardi JA. Bleeding diathesis with hemophilic arthropathy. *Applied Radiology* 2008;37(9):35-36.
28. Chirindel A, Martinez F, Gagliardi JA, Armm MF. Testicular Tuberculosis without epididymitis simulating neoplasm. *Radiology Case Reports* 2008;3(3):1-6.
29. Cho Y, Gagliardi JA, Chaddha SK. Cystic Meningioma. *Applied Radiology* 2009; 38(5):29-30.
30. Khan AA, Agarwal A, Chaddha SK, Gagliardi JA. Histiocytic sarcoma of the Terminal Ileum Presenting as a Large Ulcerating Lesion: CT Diagnosis. *Radiology Case Reports*, 2009; 4(2):262
31. Singhal A, Torstenson GE, Gagliardi JA. Celiac Artery Dissection on Computed Tomography. *Clinical Challenges and Images in GI. Gastroenterology* 2010; 139(3):733.
32. Gagliardi JA and Agarwal A. Gamekeeper's Thumb (Skier's thumb). [http://www.appliedradiology.com/Issues/2012/07/Cases/Gamekeeper's-thumb-\(Skier's-thumb\).aspx](http://www.appliedradiology.com/Issues/2012/07/Cases/Gamekeeper's-thumb-(Skier's-thumb).aspx)
33. Gagliardi, JA and Carino, M. Glenoid Bare Spot. *Applied Radiology* 2013; 42(10):29-30.

C. Reviews and Book Chapters

1. Gagliardi JA, Freestone KA, Shanley DJ. Testicular Microlithiasis: Ultrasound Appearance and Associated Complications. *Hawaii Medical Journal* 1993; 452:192-193
2. Gagliardi JA, Lengyel RJ. A Review of the Radiographic Manifestations of Gout. *Hawaii Medical Journal* 1994; 53: 40-43
3. Gagliardi JA, Radvany MG, Kilkenny TE, Russo RD. Colonic Sphincters Revisited: Simulator's of Organic Disease. *Hawaii Medical Journal* 1994; 53:278-282
4. Wilbur MJ, Gagliardi JA, Riccio GJ, Vincent NR, Haber S, Delaplain C, Eclavea A. Soft Tissue Uptake in Radionuclide Musculoskeletal Imaging. *Applied Radiology* 1997; 26(12): 30-37
5. Meyer NR, Gagliardi JA, Lawson JP. Musculoskeletal Radiology. Practical Guide of Diagnostic Imaging, CV Mosby Co., 1998, page 220-279
6. Wilbur MJ, Gagliardi JA, Lawson JP, Sobel LM. Tuberos Sclerosis: The Spectrum of Clinical and Radiographic Findings. *Postgraduate Radiology* 1999; 19:3-12
7. Lustberg H, Gagliardi JA, Lawson JP, Fugate M, Micalizzi GJ, Specht NT. Intramedullary Osteosarcoma: Radiographic Appearances and Imaging Strategies. *Radiologyweb.Com*. December Issue, 1999
8. Lustberg H, Gagliardi JA, Lawson JP, Lawson AJ, Fugate M, Specht NS, Micalizzi GJ. Surface Osteosarcoma: Radiographic Appearances and Imaging Strategies. *Radiology web.com*. January Issue, 2000
9. Lustberg H, Gagliardi JA, Lawson JP, Specht NS, Fugate M, Micalizzi GJ. Secondary Osteosarcoma. *Radiologyweb.com*. February Issue, 2000
10. Lustberg H, Gagliardi JA, Lawson JP, Kilkenny TE, Donkor D, Fugate M, Micalizzi GJ, Specht NS. Extraskelatal and Gnathic Osteosarcoma. *Radiologyweb.com*. March-April Issue, 2000

11. Gagliardi JA. Musculoskeletal Cartilage Lesions Encountered in Clinical Practice. Part One: Benign Lesions. *Radiologyweb.com*. January Issue, 2001
12. Gagliardi JA. Musculoskeletal Cartilage Lesions Encountered in Clinical Practice. Part Two: Malignant Lesions. *Radiologyweb.com*. February Issue, 2001
13. Gagliardi JA, Ibrahim S, Kumar M. Paget's Disease: Radiologic Findings. *Rheumatologyweb.com*. July Issue, 2002
14. Swain FR, Martinez F, Gripp M, Razdan R, Gagliardi JA. Traumatic complications from placement of thoracic catheters and tubes. *Emergency Radiology* 2005; 12: 11-18
15. Tagg WG, Razdan RS, Swain FR, Gagliardi JA, Chaddha SKB. Posterior Reversible Encephalopathy Syndrome Following a Cesarean Delivery: Case Report and Literature Review. *Connecticut Medicine* 2008 (72) 5: 267-269.

D. Abstract:

1. Zaheer W, Friedland ML, Cooper EB, Dorosario A, Burd R, Gagliardi JA, Torstenson G. Spontaneous Regression of Small Cell Lung Cancer Associated with Severe Neuropathy. *Connecticut Medicine* 1992; 56:623

E. Presentations:

1. Gagliardi JA, Chung E, Chandnani VP, Kesling KL, Cristensen KP, Null RN. Chondromalacia Patellae: Diagnostic Accuracy of Magnetic Resonance Imaging, Magnetic Resonance Arthrography, and Computed Arthrotomography. Society of Skeletal Radiology, Marco Island, FL. 1993
2. Chandnani VP, Harper MT, Gagliardi JA, Ficke J, Rolling L, Christensen K. Chronic Ankle Instability: Evaluation by Stress Radiography, Magnetic Resonance Imaging and Magnetic Resonance Arthrography. Society of Skeletal Radiology, Marco Island, FL. 1993
3. Chandnani VP, Yeager TD, DeBaradino TM, Christensen K, Heitz DR, Gagliardi JA, Hansen MF. Glenoid Labral Tears: A Comparison of the Diagnostic Accuracy of Magnetic Resonance Imaging, Magnetic Resonance Arthrography and Computed Arthrotomography. American Roentgen Ray Society, San Francisco, CA. 1993
4. Gagliardi JA. Reading Chest Radiographs: The Secrets. Fifth Annual Aloha Medical Conference, Honolulu, HI. 1993
5. Gagliardi JA, Radvany MG, Kilkenny TE. Colonic Sphincters Revisited: Simulators of Organic Disease. Radiological Society of North America, Chicago, IL. 1993
6. Gagliardi JA, Chung E, Chandnani VP, Kesling KL, Cristensen KP, Null RN. Chondromalacia Patellae: Diagnostic Accuracy of Magnetic Resonance Imaging, Magnetic Resonance Arthrography, and Computed Arthrotomography. Radiological Society of North America, Chicago, IL. 1993
7. Chandnani VP, Harper MT, Gagliardi JA, Ficke J, Rolling L, Christensen K. Chronic Ankle Instability: Evaluation by Stress Radiography, Magnetic Resonance Imaging and Magnetic Resonance Arthrography. Radiological Society of North America, Chicago, IL. 1993
8. Gagliardi JA, Radvany MG, Kilkenny TE. Colonic Sphincters Revisited: Simulators of Organic Disease. 18th International Congress of Radiology, Singapore. 1994
9. Bradley YC, Chandnani VP, Gagliardi JA, Yeager TD, Harper MT, Hansen MF. Magnetic Resonance Arthrography of the Musculoskeletal System. 18th International Congress of Radiology, Singapore. 1994

10. Harper MT, Chandnani VP, Evans EM, Gagliardi JA, Hansen MF. Chronic Ankle Injuries: Evaluation with MR Arthrography, MR Imaging and Conventional Imaging Techniques. Annual 42nd meeting of the Association of University Radiologists, Boston, MA. 1994
11. Chandnani VP, Spaeth J, Bradley YC, Radvany MG, DeBerardino TM, Gagliardi JA. Glenohumeral Ligaments, Glenoid Labrum and Shoulder Joint Capsule: Evaluation of Incidence and Location of Abnormalities in Patients with Instability. Radiological Society of North America, Chicago, IL. 1994
12. Gagliardi JA, Chung EM, Chandnani VP, Hansen MF. Chondromalacia Patellae: Prospective Evaluation of Relative Efficacies of Magnetic Resonance Imaging, Magnetic Resonance Arthrography and Computed Arthrography. USARPAC Asia-Pacific Military Medical Conference, New Delhi, India. 1995
13. Gagliardi JA, Chung EM, Chandnani VP, Kesling KL, Radvany MG, Hansen MF. Synovial Plicae Associated with Chondromalacia Patellae: Efficacy of MR Imaging, MR Arthrography and Computed Arthrography. European Congress of Radiology, Vienna, Austria. 1995
14. Harper MT, Murnane TG, Chandnani VP, Gagliardi JA, Spaeth JH, Boutin R. MR Imaging of Musculoskeletal Ganglia: A Pictorial Essay. European Congress of Radiology, Vienna, Austria. 1995
15. Chandnani VP, Murnane TG, Harper MT, Gagliardi JA, Bradley YC. Glenohumeral Ligaments, Glenoid Labrum and Shoulder Joint Capsule: Evaluation of Incidence and Location of Abnormalities in Patients with Instability. European Congress of Radiology, Vienna, Austria. 1995
16. Chandnani VP, Gagliardi JA, Harper MT. Glenohumeral Ligaments and Capsular Mechanism: Evaluation with MR Arthrography. The First Kuwait International Conference of Radiology and Nuclear Medicine, Kuwait. 1995
17. Gagliardi JA, Chung EM, Chandnani VP, Kesling KL, Radvany MG, Hansen MF. Synovial Plicae Associated with Chondromalacia Patellae: Efficacy of MR Imaging, MR Arthrography and Computed Arthrography. American Roentgen Ray Society, Washington, DC. 1995
18. Chandnani VP, Bradley YC, Gagliardi JA, Murnane TG, DeBerardino TM. Glenohumeral Ligaments and Shoulder Capsular Mechanism: Evaluation with MR Arthrography. Roentgen Centenary Congress, Birmingham, England. 1995
19. Payne CE, Gagliardi JA, Jezior JR, Deshon GE. The Use of Phased Array Coil MR Imaging for Staging of Clinically Localized Adenocarcinoma of the Prostate. 43rd Annual J. C. Kimbrough Urological Seminar, Washington, DC. 1995
20. Gagliardi JA, Vincent NM, Wilbur MJ, Delaplain C, Eclavea A. Soft Tissue Uptake in Radionuclide Musculoskeletal Imaging. 19th International Congress of Radiology, Beijing, China. 1996
21. Gagliardi JA, Riccio GJ, Eclavea A. Pitfalls in Hysterosalpingographic Interpretation. 19th International Congress of Radiology, Beijing, China. 1996
22. Gagliardi JA, Wilbur MJ, Lawson JP, Eclavea A, Sobel LM. Tuberos Sclerosis: The Spectrum of Clinical and Radiographic Findings. 19th International Congress of Radiology, Beijing, China. 1996
23. Gagliardi JA, Riccio GJ. Pitfalls in Hysterosalpingographic Interpretation. . Radiological Society of North America, Chicago, IL. 1996
24. Gagliardi JA, Wilbur MJ, Lawson JP, Eclavea A, Sobel LM. Tuberos Sclerosis: The Spectrum of Clinical and Radiographic Findings. Radiological Society of North America, Chicago, IL. 1996

25. Payne CE, Gagliardi JA, Jezior JR, Deshon GE. The Use of Phased Array Coil MR Imaging for Staging of Clinically Localized Adenocarcinoma of the Prostate. Western Section of American Urological Association, San Diego, CA. 1996
26. Gagliardi JA, Vincent NM, Wilbur MJ, Delaplain C, Eclavea A. Soft Tissue Uptake in Radionuclide Musculoskeletal Imaging. American Roentgen Ray Society, Boston, MA. 1997
27. Gagliardi JA, Lawson JP, Bonnet AL, Fugate MJ, Micalizzi GJ. Parosteal Lipoma: A Review of the Clinical and Radiographic Findings. Radiological Society of North America, Chicago, IL. 1997
28. Gagliardi JA. Genitourinary System Trauma: Classification and Management Strategies. St. Vincent's College, Bridgeport, CT. 1998
29. Gagliardi JA, Lustberg H, Lawson JP, Specht N, Fugate MJ, Micalizzi GJ. Osteosarcoma: The Radiologic Appearances and Imaging Strategies. American Roentgen Ray Society, New Orleans, LA. 1999
30. Gagliardi JA. One Week Genitourinary and Musculoskeletal Review. Visiting Consultant: Tripler Army Medical Center, Honolulu, HI. March 20-24, 2000
31. Gagliardi JA. Magnetic Resonance Imaging of the Knee. Professional Development Course & Health Care Career Certificate Program, St. Vincent's College, Bridgeport, CT. September 25, 2002
32. Gagliardi JA. X-Ray Callbacks in the Emergency Department. Emergency Medicine Grand Rounds, St. Vincent's Medical Center, Bridgeport, CT. March 19, 2003
33. Gagliardi JA. Breast Calcifications on Mammography: Characterization and Management. Professional Development Course & Health Care Career Certificate Program, St. Vincent's College, Bridgeport, CT. March 27, 2004
34. Gagliardi JA. Understanding the BI-RADS Lexicon in Mammography. Professional Development Course & Health Care Career Certificate Program, St. Vincent's College, Bridgeport, CT. March 27, 2004
35. Gripp MJ, Coleman B, Tangri R, Udeshi M, Gagliardi JA. Review of Iatrogenic Trauma to the Thorax. American Roentgen Ray Society, Miami FL. 2004
36. Gripp MJ, Gagliardi JA, Russo G, Callahan T. A Patterned Approach for Evaluating Patients with Arthritis. International Congress of Radiology, Montreal, Canada. 2004
37. Gripp MJ, Tangri R, Coleman B, Gagliardi JA. A Review of Iatrogenic Trauma to the Thorax. International Congress of Radiology, Montreal, Canada. 2004
38. Gripp MJ, Bangash H, Russo G, Callahan T, Gagliardi JA. A Patterned Approach for Evaluating Patients with Arthritis of the Extremities. RANZCR Annual Scientific Meeting, Perth, Australia. 2004
39. Gagliardi JA. Shoulder MRI: Imaging Protocols, Normal and Abnormal Findings. Professional Development Course & Health Care Career Certificate Program, St. Vincent's College, Bridgeport, CT. April 25, 2005
40. Coleman B, Kleysler-Sugrue K, Passeri D, Gagliardi J. The Safe and Effective use of Lidocaine with Epinephrine for Stereotactic Breast Biopsy. European Congress of Radiology, Vienna, Austria. 2007
41. Coleman B, Kleysler-Sugrue K, Passeri D, Gagliardi J. The Safe and Effective use of Lidocaine with Epinephrine for Stereotactic Breast Biopsy. Association of University Radiologists Conference. Denver, Colorado. 2007

42. Conklin PS, Gagliardi JA, Swain FR. MR Findings in Acute Brachial Neuritis (Parsonage-Turner Syndrome). Association of University Radiologists Conference. Seattle, Washington. 2008
43. El-Haddad G, Olsavsky TD, Gagliardi JA. Altered Biodistribution of FDG can lead to incorrect diagnoses on FDT-PET: Important of Patient Preparation and Pre Scan Interventions. ST. Vincent's Medical Center Department of Medical Education 5th Annual Science Symposium. Bridgeport, Connecticut. 2009
44. Tagg W, Amankona R, Razdan R, Mejia V, Gagliardi JA. Diffuse Alveolar Hemorrhage after Abciximab Use. ST. Vincent's Medical Center Department of Medical Education 5th Annual Science Symposium. Bridgeport, Connecticut. 2009
45. Martinez F, Razdan R, Armm MF, Chirindel A, Gagliardi JA. Testicular Tuberculosis without Epidydimitis Simulating Neoplasm. ST. Vincent's Medical Center Department of Medical Education 5th Annual Science Symposium. Bridgeport, Connecticut. 2009
46. Agarwal A, Chhatwal A, Gagliardi J. Pulmonary Hemorrhage following Tracheal Extubation. American College of Physicians Meeting. Southington, Connecticut. 2009
47. Perez JC, Razdan RN, Gagliardi JA. Radiation Induced Myonecrosis Mimicking a Lower Extremity Abscess. American College of Physicians Meeting. Southington, Connecticut. 2009
48. Visiting Physician Consultant, Tripler Army Medical Center. ABR Musculoskeletal Board Review. Honolulu Hawaii. 2011.
49. Visiting Physician Consultant, Tripler Army Medical Center. ABR Musculoskeletal Board Review. Honolulu Hawaii. 2012.
50. Visiting Physician Consultant, SUNY Downstate Medical Center. ABR Musculoskeletal Board Review. Brooklyn, New York. 2012
51. Specht ES, Gagliardi JA. Common Shoulder Injuries: provider examination, imaging and physical therapy intervention. Webinar for Concentra Inc. March 2013.
52. Visiting Physician Consultant, SUNY Downstate Medical Center. What you need to know to practice MSK radiology. Brooklyn, New York. 2013.

JOANNE E. ELDRIDGE B.S. R.T. (R) (MR)
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Objective: To obtain a challenging position in the MRI field that best utilizes my experience and education and has excellent opportunities for advancement.

Employment History

2012-Present MRI Senior Tech/Supervisor

In addition to being a working tech, also responsible for scheduling staff in two offices for tech and desk coverage. Collaborate with the radiologists in the design of the MRI protocols, order supplies, schedule PMs and cryogen fills, manage equipment failures, Mentor, train and coach all new technologists and Quinnipiac students, evaluate student competencies update training manuals, manage all technical aspects of ACR accreditation, monitor expiration dates of contrast injectables
Trained all MRI staff on Greenway system and extended training to anyone needing assistance in ordering MRI exams.

2006- Present Connecticut Orthopaedic Specialists Branford, CT

MRI Tech

Perform examinations , of the spine, pelvis, hip, femur, knee, tib-fib, ankle, foot, shoulder, humerus, elbow, forearm, wrist and hand for orthopaedic
Evaluation using GE 1 Tesla and 1.5 Tesla

Consistent production of high quality diagnostic images while working independently
Maintained high standard for patient MRI safety including pre-screening for contra-
indications

X RAY TECH

Fill in as the Ortho Now tech as needed. Cover surgery center on last minutes notice for surgeries and epidural injections.

2004-2006 Connecticut Orthopaedic Specialists Hamden, CT

MRI Tech

Perform examinations of the knee down and elbow down on ONI extremity unit.

2000-2004 Connecticut Orthopaedic Specialists Guilford, CT

X-Ray Tech

Perform routine orthopedic examinations.

1997-2000 Stay at home Mom

1994-1997 Osteoporosis and Diagnostic Treatment Center, Hamden, CT

Bone Density Tech

Perform bone density exams for private and research study protocols using Hologic machine.

1991-1993 Home X-ray, New Haven, CT

CT Tech

Perform CT examinations with and without contrast.

1989-1991 Radiology Group, Hamden, Ct

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X-ray/CT Tech

Perform routine x-rays, fluoro, mammography, and CT exams.

1988-1989 Yale New Haven Hospital, New Haven, Ct

X-Ray Tech

Perform routine x-ray examinations while rotating through fluoro, portables, pediatrics, bone densitometry, orthopedics, OR.

Education:

B.S., Radiologic Sciences, 1988

Quinnipiac University, Hamden, CT

References:

Dr Joseph Gagliardi, St Vincent's Medical Center Residency Director 203-576-5061

Teresa Ostrander, St Mary's MRI Chief Tech/Director 203-709-3674

Lori Baldwin, Connecticut Orthopaedic Specialists Dr's Assistant 203-407-3518

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Curriculum Vitae

Billie Jo Foraker
101 Bailey Road
North Haven, CT
(203) 619-2607

EDUCATION:

Gateway Community College, New Haven, CT

- Certified Nurse Assistant 1989
- Associate Degree in Science 1995
- Radiological internship YNH 1993-1995
- Radiological certification & CT State license granted 1995

EMPLOYMENT:

2015- present: Connecticut Orthopaedic Specialists, P.C. Hamden CT

- Clinical Office Manager – Hamden location
 - Management of front desk, X-ray and medical assistant personal
 - Responsible for clinical and front desk operations for COS Hamden office
- Radiology Manager – COS Division
 - Supervisor of x-ray for 7 clinical locations
 - Responsible for clinical staff allocations, maintenance of licensure for staff and radiological equipment

2008 - 2015 : Connecticut Orthopaedic Specialists, P.C. Hamden CT

- Medical Administrative Assistant for Dr. Philip Minotti
 - Instrumental in development Dr. Minotti patient practice
 - Responsible for management of all patient communication, including lab, imaging results and surgical equipment
 - Pre cert and booked surgical cases for joint reconstruction cases performed at YNH
 - Managed referral relationship(s) into Dr. Minotti from outside primary care referral physicians

1989 to 2008: New Haven Orthopaedic Group P.C.
Connecticut Orthopaedic Specialists, P.C.,

- Receptionist & clinical floater 1989-1995
- Billing & Collections 1989-1993
- Physical Therapy aide 1993-1995
- X Ray Technician 1995- 2008
 - Lead X Ray Tech Hamden, responsible for managing all supplies for clinical rooms and x-ray suite

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LICENSES / CERTIFICATIONS / COURSE WORK :

Certified Nursing Assistant 1989
Connecticut X Ray License 1995
Certified Medical Assistant June 2013
Greenway Practice Management training program 2015
PC and Apple Software formats

OUTSIDE INTERESTS :

- Freelance photographer
- Equestrian
 - Horse owner & trainer
 - Member of Cheshire Horse Counsel

Carlene Fox RT (R)(MR)

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Meriden, CT 06450
Cell: 203-671-0786
cmg611@yahoo.com

Education/Job Experience

Quinnipiac University, Hamden, CT
Bachelor of Science in Diagnostic Imaging
Advanced Specialization in MRI
Board Certified X-Ray and MRI Technologist
A.A.M.A certified
Currently employed at Connecticut Orthopedic Specialist as a MRI Technologist

Qualifications

Clinical Skills

- 10 years of working experience in MRI
- Setting up and performing routine MRI scans
- Proper MRI coil selection
- Knowledge of GE and ONI MRI systems
- Archiving images and creating MRI CD's
- Completing patient and procedure information using PACS systems (Fusion, Efilm, and Viztek)
- Weekly QA Testing
- Knowledge of Greenway/Primesuite chart systems

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Curriculum Vitae

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EDUCATION:

Springfield College, Springfield, Massachusetts ; BS, Biology, June 1978

University of Pennsylvania, Philadelphia, PA. ; Certificate, Physical Therapy May 1979

Sacred Heart University, Fairfield, CT ; Masters of Business Administration, May 1992

EMPLOYMENT:

1993 to present : Connecticut Orthopaedic Specialists, P.C. ,
Sports Therapy & Rehabilitation
Temple Physical Therapy & Cardiac Rehabilitation,
Hamden, CT

- Chief Executive Officer

1991 to 1993 : Neurosurgery Associates of Northwest CT, P.C., Waterbury, CT

- Practice Administrator

1985 to 1993 : Immediate Medical Care & Connecticut Physical Therapy & SportsMedicine

- Director of Operations
- Director of Physical Therapy

1979 to 1985 : Private Practice Physical Therapist

1990 to present ; Owner / Operator , Quality Assurance Reviews

- Physical Therapy peer review company
Documentation review and authorization services to managed care industry

LICENSES ;

Connecticut Physical Therapy License # 002530

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EXHIBIT E

COS submits "The Big Idea: How to Solve the Cost Crisis in Health Care" written by Robert S. Kaplan and Michael E. Porter from the September 2011 issue of the Harvard Business Review. The article is pertinent because COS is in the process of moving its billing practice from a fee-for-service arrangement, where each component of the orthopedic treatment is billed individually, to a "bundled payment" system where the cost involved in the most common orthopedic procedures can be bundled into one payment. This article sets forth the benefits of cutting costs without losing value – and the focus on a patient's health care result.

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COSTS

The Big Idea: How to Solve the Cost Crisis in Health Care

by Robert S. Kaplan and Michael E. Porter

FROM THE SEPTEMBER 2011 ISSUE

Watch the video interview with Robert S. Kaplan and Michael E. Porter, "Solving the Health Care Cost Crisis."

Listen to an interview with Robert S. Kaplan.

14:42

US. health care costs currently exceed 17% of GDP and continue to rise. Other countries spend less of their GDP on health care but have the same increasing trend. Explanations are not hard to find. The aging of populations and the development of new treatments are behind some of the increase. Perverse incentives also contribute: Third-party payors (insurance companies and governments) reimburse for procedures performed rather than outcomes achieved, and patients bear little responsibility for the cost of the health care services they demand.

But few acknowledge a more fundamental source of escalating costs: the system by which those costs are measured. To put it bluntly, there is an almost complete lack of understanding of how much it costs to deliver patient care, much less how those costs compare with the outcomes achieved. Instead of focusing on the costs of treating individual patients with specific medical conditions over their full cycle of care, providers aggregate and analyze costs at the specialty or service department level.

Making matters worse, participants in the health care system do not even agree on what they mean by costs. When politicians and policy makers talk about cost reduction and "bending the cost curve," they are typically referring to how much the government or insurers pay to providers—not to the costs incurred by providers to deliver health care services. Cutting payor reimbursement does reduce the bill paid by insurers and lowers providers' revenues, but it does nothing to reduce the actual costs of delivering care. Providers share in this confusion. They often allocate their costs to procedures, departments, and services based not on the actual resources used to deliver care but on how much they are reimbursed. But reimbursement itself is based on arbitrary and inaccurate assumptions about the intensity of care.

Poor costing systems have disastrous consequences. It is a well-known management axiom that what is not measured cannot be managed or improved. Since providers misunderstand their costs, they are unable to link cost to process improvements or outcomes, preventing them from making systemic and sustainable cost reductions. Instead, providers (and payors) turn to simplistic actions such as across-the-board cuts in expensive services, staff compensation, and head count. But imposing arbitrary spending limits on discrete components of care, or on specific line-item expense categories, achieves only marginal savings that often lead to higher total systems costs and poorer outcomes. For example, as payors introduce high copayments to limit the use of expensive drugs, costs may balloon elsewhere in the system should patients' overall health deteriorate and they subsequently require more services.

Poor cost measurement has also led to huge cross-subsidies across services. Providers are generously reimbursed for some services and incur losses on others. These cross-subsidies introduce major distortions in the supply and efficiency of care. The inability to properly measure

cost and compare cost with outcomes is at the root of the incentive problem in health care and has severely retarded the shift to more effective reimbursement approaches.

Finally, poor measurement of cost and outcomes also means that effective and efficient providers go unrewarded, while inefficient ones have little incentive to improve. Indeed, institutions may be penalized when the improvements they make in treatments and processes reduce the need for highly reimbursed services. Without proper measurement, the healthy dynamic of competition—in which the highest-value providers expand and prosper—breaks down. Instead we have zero-sum competition in which health care providers destroy value by focusing on highly reimbursed services, shifting costs to other entities, or pursuing piecemeal and ineffective line-item cost reductions. Current health care reform initiatives will exacerbate the situation by increasing access to an inefficient system without addressing the fundamental value problem: how to deliver improved outcomes at a lower total cost.

The remedy to the cost crisis does not require medical science breakthroughs or new governmental regulation. It simply requires a new way to accurately measure costs and compare them with outcomes.

Fortunately, we can change this state of affairs. And the remedy does not require medical science breakthroughs or top-down governmental regulation. It simply requires a new way to accurately measure costs and compare them with outcomes. Our approach makes patients and their conditions—not departmental units, procedures, or services—the fundamental unit of analysis for measuring costs and outcomes. The experiences of several major institutions currently implementing the new approach—the Head and Neck Center at MD Anderson Cancer Center in Houston, the Cleft Lip and Palate Program at Children’s Hospital in Boston, and units performing knee replacements at Schön Klinik in Germany and Brigham & Women’s Hospital in Boston—confirm our belief that bringing accurate cost and value measurement practices into health care delivery can have a transformative impact.

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Understanding the Value of Health Care

The proper goal for any health care delivery system is to improve the value delivered to patients. Value in health care is measured in terms of the patient outcomes achieved per dollar expended. It is not the number of different services provided or the volume of services delivered that matters but the value. More care and more expensive care is not necessarily better care.

To properly manage value, both outcomes and cost must be measured at the patient level. Measured outcomes and cost must encompass the entire cycle of care for the patient's particular medical condition, which often involves a team with multiple specialties performing multiple interventions from diagnosis to treatment to ongoing management. A medical condition is an interrelated set of patient circumstances that are best addressed in a coordinated way and should be broadly defined to include common complications and comorbidities. The cost of treating a patient with diabetes, for example, must include not only the costs associated with endocrinological care but also the costs of managing and treating associated conditions such as vascular disease, retinal disease, and renal disease. For primary and preventive care, the unit of value measurement is a particular patient population—that is, a group with similar primary care needs, such as healthy children or the frail and elderly with multiple chronic conditions.

Let's explore the first component of the health care value equation: health outcomes. Outcomes for any medical condition or patient population should be measured along multiple dimensions, including survival, ability to function, duration of care, discomfort and complications, and the sustainability of recovery. Better measurement of outcomes will, by itself, lead to significant improvements in the value of health care delivered, as providers' incentives shift away from performing highly reimbursed services and toward improving the health status of patients. Approaches for measuring health care outcomes have been described previously, notably in Michael Porter's 2010 *New England Journal of Medicine* article, "What Is Value in Health Care?"

While measuring medical outcomes has received growing attention, measuring the costs required to deliver those outcomes, the second component of the value equation, has received far less attention. In the value framework, the relevant cost is the total cost of all resources—clinical and administrative personnel, drugs and other supplies, devices, space, and equipment—used during

a patient's full cycle of care for a specific medical condition, including the treatment of associated complications and common comorbidities. We increase the value of health care delivered to patients by improving outcomes at similar costs or by reducing the total costs involved in patients' care while maintaining the quality of outcomes.

A powerful driver of value in health care is that better outcomes often go hand in hand with lower total care cycle costs. Spending more on early detection and better diagnosis of disease, for example, spares patients suffering and often leads to less complex and less expensive care later. Reducing diagnostic and treatment delays limits deterioration of health and also lowers costs by reducing the resources required for care. Indeed, the potential to improve outcomes while driving down costs is greater in health care than in any other field we have encountered. The key to unlocking this potential is combining an accurate cost measurement system with the systematic measurement of outcomes. With these powerful tools in place, health care providers can utilize medical staff, equipment, facilities, and administrative resources far more efficiently, streamline the path of patients through the system, and select treatment approaches that improve outcomes while eliminating services that do not.

The Challenges of Health Care Costing

Accurate cost measurement in health care is challenging, first because of the complexity of health care delivery itself. A patient's treatment involves many different types of resources—personnel, equipment, space, and supplies—each with different capabilities and costs. These resources are used in processes that start with a patient's first contact with the organization and continue through a set of clinical consultations, treatments, and administrative processes until the patient's care is completed. The path that the patient takes through the system depends on his or her medical condition.

The already complex path of care is further complicated by the highly fragmented way in which health care is delivered today. Numerous distinct and largely independent organizational units are involved in treating a patient's condition. Care is also idiosyncratic; patients with the same condition often take different paths through the system. The lack of standardization stems to some extent from the artisanal nature of medical practice—physicians in the same organizational

unit performing the same medical process (for instance, total knee replacement) often use different procedures, drugs, devices, tests, and equipment. In operational terms, you might describe health care today as a highly customized job shop.

Existing costing systems, which measure the costs of individual departments, services, or support activities, often encourage the shifting of costs from one type of service or provider to another, or to the payor or consumer. The micromanagement of costs at the individual organizational unit level does little to reduce total cost or improve value—and may in fact destroy value by reducing the effectiveness of care and driving up administrative costs. (For more on the problems with current costing systems, see the three Myth sidebars.)

Myth #1: Charges are a good surrogate for provider costs.

The widespread confusion between what a provider charges, what it is actually reimbursed, and its costs is a major barrier to reducing the cost of health care. Providers have aggravated this problem by structuring important aspects of their costing systems around the way they are reimbursed. In the U.S., this is partly a historical artifact of the Medicare cost-plus reimbursement system, which requires hospital departments to prepare an annual Medicare Cost Report (MCR), detailing costs and charges by department. Rather than developing and maintaining accurate costing systems that are based on actual resource usage, separate from the regulatory standard required for reimbursement, hospitals defaulted to reimbursement-driven systems.

Unfortunately, that approach was flawed from the start because it was based on the use of highly aggregate data for

Myth #2: Hospital overhead costs are too complex to allocate accurately.

Most health care leaders will eventually accept the idea that the direct costs of patient care, such as nurses, physicians, and consumable supplies (drugs, bandages, and syringes), ought to be assigned more accurately to individual patients. But many leaders believe that allocating the costs of indirect and support units cannot be done except with crude, arbitrary methods, often dressed up to look sophisticated. Typically, they use a “peanut butter” method, which spreads overhead and support costs across each department’s billable activities (see Myth #1) using metrics such as the size of direct costs, head count, length of stay, assigned physical space, number of patients, number of procedures, RVUs supplied, or costs-to-charge ratios (Myth #1 again).

estimating costs and the deeply flawed assumption that every billable event in a department has the same profit margin. Reimbursement-based costing also buries the costs of valuable but nonbillable events, such as patient consultations, in large overhead pools that are allocated arbitrarily and inaccurately to billable events.

Although costing systems for physician services differ from those used by hospitals, they suffer from the same problems. As is the case for hospitals, U.S. physicians are reimbursed not on the basis of an individual patient's resource use but on average estimates of relative demands—relative value units, or RVUs—on physician labor, practice expenses, and malpractice expenses in performing billable activities. These resource estimates are derived from specialty panels and national surveys of physicians, who stand to gain from overestimating the time and complexity of their work. Despite the required sign-off by government payors, the RVU estimates are not systematically measured or confirmed in practice settings. Reimbursing physicians on the basis of highly aggregate and likely inaccurate estimates of their costs introduces major incentive problems into the health care system. But the problems are compounded when the reimbursement rates are also used to allocate physician costs to patients, a purpose for which they were never intended.

We need to abandon the idea that charges billed or reimbursements paid in any way reflect costs. In reality, the cost

The effect of such arbitrary support-department allocations on the measured cost of services can be profound. In the past, Schön Klinik, like other hospitals in Germany, had reduced the capacity of its total knee replacement rehabilitation units in part because the existing cost system portrayed them as less profitable than acute-care units. During Schön Klinik's cost pilot, the project team discovered that the existing cost system allocated support-department costs largely on the basis of length of patient stay, not on the patient's use of support resources. Since Schön total knee replacement patients spent 75% of their stay in the rehab facility, rehab had been allocated about 75% of support department costs.

The TDABC analysis showed, however, that the demand for many support-unit services, such as medical billing, is far higher during the days a patient spends in the acute-care facility than during rehab days. With support costs properly assigned, the rehab facility showed improved profitability. Schön Klinik began to contemplate the expansion of its rehabilitation capacity—a complete reversal of its previous decision—and shifted its focus more intensively on reducing support costs incurred during the acute-care stay.

Once indirect costs have been accurately

Myth #3: Most health care costs are fixed.

of using a resource—a physician, nurse, case manager, piece of equipment, or square meter of space—is the same whether the resource is performing a poorly or a highly reimbursed service. Cost depends on how much of a resource's available capacity (time) is used in the care for a particular patient, not on the charge or reimbursement for the service, or whether it is reimbursed at all.

Many health care system participants, including economists and accountants, believe that most costs in health care are fixed because so much care is delivered using shared staff, space, and equipment. The result of this misguided thinking is that cost reduction efforts tend to focus on only the small fraction of costs seen as variable, such as drugs and supplies, which are sometimes referred to as marginal or incremental costs. This myth also motivates some health care organizations to expand through mergers, acquisitions, and organic growth in order to reap economies of scale by spreading their fixed costs over an increased volume of business.

But if most health care costs were truly fixed, we would not have the health care cost problem we do today. If most costs were fixed, growth in demand for health care would increase only that small fraction of costs that are variable, leading to lower average costs in the system, not the dramatically higher share of GDP now being devoted to health care.

To understand why most health care costs are not fixed, start with personnel costs, which are generally at least 50% of the total costs of health care providers, according to American Hospital Association statistics. Hint: Personnel costs are not fixed. Hospital executives can set the quantity, mix, and compensation of their personnel each year, or even more frequently. Personnel costs are fixed only when executives allow them to be. The claim that

personnel costs are fixed is a reflection of management inattention, not of the nature of those costs.

Space costs are also not fixed. Space is perhaps an organization's most fungible resource. If demand for space is reduced, units can be consolidated into smaller space, and excess space can be repurposed, sold, or subleased. Similarly, equipment costs can be avoided if changes in processes, treatment protocols, or patient mix eliminate the demand for the resources. Equipment no longer needed can be retired or sold to other health care institutions that are expanding their capacity.

All told, we estimate that upwards of 95% of what health care managers think of as fixed costs are actually under their control and therefore not really fixed.

Any accurate costing system must, at a fundamental level, account for the total costs of all the resources used by a patient as she or he traverses the system. That means tracking the sequence and duration of clinical and administrative processes used by individual patients—something that most hospital information systems today are unable to do. This deficiency can be addressed; technology advances will soon greatly improve providers' ability to track the type and amount of resources used by individual patients. In the meantime, it is possible to determine the predominant paths followed by patients with a particular medical condition, as our pilot sites have done.

With good estimates of the typical path an individual patient takes for a medical condition, providers can use the time-driven activity-based costing (TDABC) system to assign costs accurately and relatively easily to each process step along the path. This improved version of

activity-based costing requires that providers estimate only two parameters at each process step: the cost of each of the resources used in the process and the quantity of time the patient spends with each resource. (See Robert S. Kaplan and Steven R. Anderson's "Time-Driven Activity-Based Costing," HBR 2004.)

In its initial implementation, such a costing system may appear complex. But the complexity arises not from the methodology but from today's idiosyncratic delivery system, with its poorly documented processes for treating patients with particular conditions and its inability to map asset and expense categories to patient processes. As health care providers begin to reorganize into units focused on conditions, standardize their protocols and treatment processes, and improve their information systems, using the TDABC system will become much simpler.

To see how TDABC works in the health care context, we first explore a simplified example.

Costing the Patient: A Simple Example

Consider Patient Jones, who makes an outpatient visit to a clinic. To estimate the total cost of Jones's care, we first identify the processes he undergoes and the resources used in each process. Let's assume that Jones uses an administrative process for check-in, registration, and obtaining documentation for third-party reimbursement; and a clinical process for treatment. Just three clinical resources are required: an administrator (Allen), a nurse (White), and a physician (Green).

We begin by estimating the first of the two parameters: the quantity of time (capacity) the patient uses of each resource at each process. From information supplied by the three staffers, we learn that Jones spent 18 minutes (0.3 hours) with Administrator Allen, 24 minutes (0.4 hours) with Nurse White for a preliminary examination, and nine minutes (0.15 hours) with Physician Green for the direct examination and consultation.

Next, we calculate the capacity cost rate for each resource—that is, how much it costs, per hour or per minute, for a resource to be available for patient-related work—using the following equation:

$$\text{Capacity Cost Rate for Resource} = \frac{\text{Expenses Attributable to Resource}}{\text{Available Capacity of Resource}}$$

The numerator aggregates all the costs associated with supplying a health care resource, such as Allen, White, or Green. It starts with the full compensation of each person, including salary, payroll taxes, and fringe benefits such as health insurance and pensions. To that we add the costs of all other associated resources that enable Allen, White, and Green to be available for patient care. These typically include a pro rata share of costs related to employee supervision, space (the offices each staffer uses), and the equipment, information technology, and telecommunications each uses in the normal course of work. In this way, the cost of many of the organization's shared or support resources can be assigned to the resources that directly interact with the patient.

Supervision cost, for example, can be calculated on the basis of how many people a manager supervises. Space costs are a function of occupancy area and rental rates; IT costs are based on an individual's use of computers and communications products and services. Assume that we find Nurse White's total cost to be as follows:

Annual compensation (including fringe benefits)	\$65,000
Supervision cost (10% of nursing supervisor's full cost)	\$9,000
Occupancy (9 sq. meters of space @ \$1,200/sq. meter/year)	\$10,800
Technology and support	\$2,560
Annual total cost of Nurse White	\$87,360
Monthly total cost of Nurse White	\$7,280

We next calculate Nurse White's availability for patient care—the denominator of our capacity cost rate equation. This calculation starts with 365 days per year and subtracts all the time that the employee is not available for work. The calculation for Nurse White is as follows:

Start with	365 days per year
less weekend days	104
less vacation days	20
less holidays	12
less sick days	5
<hr/>	
	224 available days per year
	18.7 days per month

Start with	7.5 hours per available day
less scheduled breaks (hours)	0.5
less meetings, training, education	1.0
<hr/>	
Available clinical hours	6 hours per day

Nurse White is therefore available for patient work 112 hours per month (6 hours a day for 18.7 days). Dividing the monthly cost of the resource (\$7,280) by monthly capacity (112 hours) gives us Nurse White's capacity cost rate: \$65 per hour.

Let's assume that similar calculations yield capacity cost rates for Administrator Allen and Physician Green of \$45 per hour and \$300 per hour, respectively.

We calculate the total cost of Jones's visit to the facility by simply multiplying the capacity cost rate of each resource by the time (in hours) Jones spent using the resource, and then adding up the components:

(0.3 hours × \$45)
(0.4 hours × \$65)
+ (0.15 hours × \$300)
<hr/>
Total cost of visit: \$84.50

As this example demonstrates, accurately calculating the cost of delivering health care is quite straightforward under the TDABC system. Although the example is admittedly simplified, it captures almost all the fundamental concepts any health care provider needs to apply to estimate the cost of treating patients over their full cycles of care.

By capturing all the costs over the complete cycle of care for an individual patient's medical condition, we allow providers and payors to address virtually any costing question. Providers can aggregate and analyze patients' cost of care by age, gender, and comorbidity, or by treatment

facility, physician, employer, and payor. They can calculate total and average costs for any category or subcategory of patients while still capturing the detailed data on individual patients needed to understand the sources of cost variation within each category.

The Cost Measurement Process

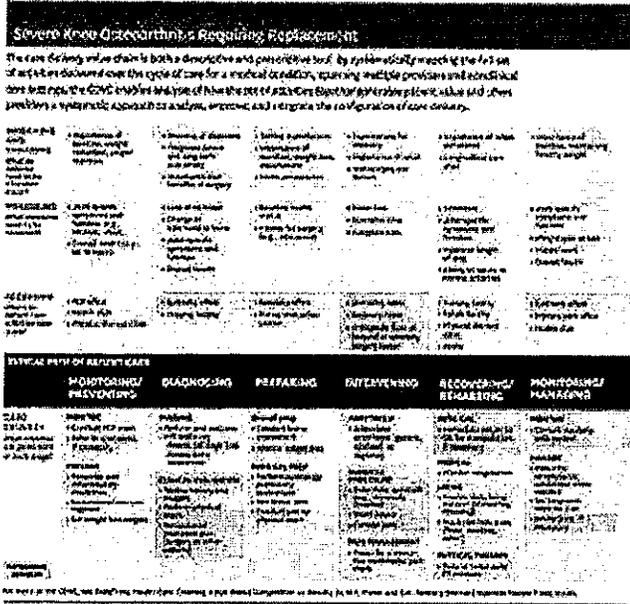
Moving beyond the simplified example, let's now look at the seven steps our pilot sites are using to estimate the total costs of treating their patient populations.

1. Select the medical condition.

We begin by specifying the medical condition (or patient population) to be costed, including the associated complications and comorbidities that affect processes and resources used during the patient's care. For each condition, we define the beginning and end of the patient care cycle. For chronic conditions, we choose a care cycle for a period of time, such as a year.

2. Define the care delivery value chain.

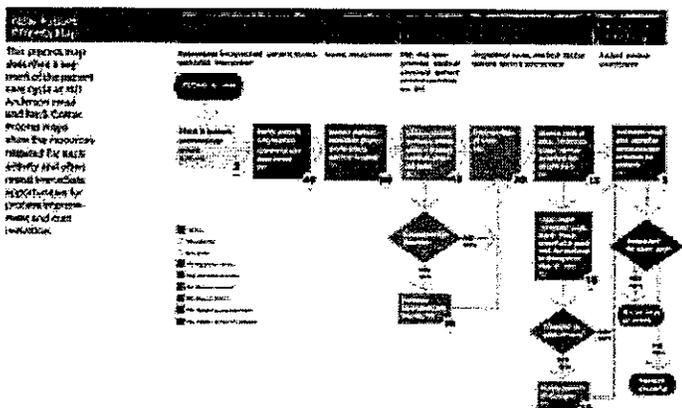
Next, we specify the care delivery value chain (CDVC), which charts the principal activities involved in a patient's care for a medical condition along with their locations. The CDVC focuses providers on the full care cycle rather than on individual processes, the typical unit of analysis for most process improvements and lean initiatives in health care. (The exhibit "The Care Delivery Value Chain" shows the CDVC developed with the Brigham & Women's pilot site for patients with severe knee osteoarthritis.) This overall view of the patient care cycle helps to identify the relevant dimensions along which to measure outcomes and is also the starting point for mapping the processes that make up each activity.



Click here for a larger image of the graphic.

3. Develop process maps of each activity in patient care delivery.

Next we prepare detailed process maps for each activity in the care delivery value chain. Process maps encompass the paths patients may follow as they move through their care cycle. They include all the capacity-supplying resources (personnel, facilities, and equipment) involved at each process along the path, both those directly used by the patient and those required to make the primary resources available. (The exhibit “New-Patient Process Map” shows a process map for one segment of the patient care cycle at the MD Anderson Head and Neck Center.) In addition to identifying the capacity-supplying resources used in each process, we identify the consumable supplies (such as medications, syringes, catheters, and bandages) used directly in the process. These do not have to be shown on the process maps.



Click here for a larger image of the graphic.

Our pilot sites used several approaches for creating process maps. Some project teams interviewed clinicians individually to learn about patient flow, while others organized “power meetings” in which people from multiple disciplines and levels of management discussed the process together. Even at this early stage in the project, the sessions occasionally identified immediate opportunities for process and cost improvement.

4. Obtain time estimates for each process.

We also estimate how much time each provider or other resource spends with a patient at each step in the process. When a process requires multiple resources, we estimate the time required by each one.

For short-duration, inexpensive processes that vary little across patients, we recommend using standard times (rather than investing resources to record actual ones). Actual duration should be calculated for time-consuming, less predictable processes, especially those that involve multiple physicians and nurses performing complex care activities such as major surgery or examination of patients with complicated medical circumstances.

TDABC is also well suited to capture the effect of process variation on cost. For example, a patient who needs a laryngoscopy as part of her clinical visit requires an additional process step. The time estimate and associated incremental resources required can be easily added to the overall time equation for that patient. (See again the process map exhibit.)

To estimate standard times and time equations, our pilot sites have found it useful to bring together all the people involved in a set of processes for focused discussion. In the future, we expect providers will use electronic handheld, bar-code, and RFID devices to capture actual times, especially if TDABC becomes the generally accepted standard for measuring the cost of patient care.

5. Estimate the cost of supplying patient care resources.

In this step, we estimate the direct costs of each resource involved in caring for patients. The direct costs include compensation for employees, depreciation or leasing of equipment, supplies, or other operating expenses. These data, gathered from the general ledger, the budgeting system,

and other IT systems, become the numerator for calculating each resource's capacity cost rate.

We must also account for the time that many physicians, particularly in academic medical centers, spend teaching and doing research in addition to their clinical responsibilities. We recommend estimating the percentage of time that a physician spends on clinical activities and then multiplying the physician's compensation by this percentage to obtain the amount of pay accounted for by the physician's clinical work. The remaining compensation should be assigned to teaching and research activities.

Next, we identify the support resources necessary to supply the primary resources providing patient care. For personnel resources, as illustrated in the Patient Jones example, these include supervising employees, space and furnishings (office and patient treatment areas), and corporate functions that support patient-facing employees. When calculating the cost of supplies, we include the cost of the resources used to acquire them and make them available for patient use during the treatment process (for instance, purchasing, receiving, storage, sterilization, and delivery).

Finally, we need to allocate the costs of departments and activities that support the patient-facing work. We map those processes as we did in step 3 and then calculate and assign costs to patient-facing resources on the basis of their demands for the services of these departments, using the process that will be described in step 6.

This approach to allocating support costs represents a major shift from current practice. To illustrate, let's compare the allocation of the resources required in a centralized department to sterilize two kinds of surgical tool kits, those used for total knee replacement and those used for cardiac bypass. Existing cost systems tend to allocate higher sterilization costs to cardiac bypass cases than to knee replacement cases because the charges (or direct costs) are higher for a cardiac bypass than for a knee replacement. Under TDABC, however, we have learned that more time and expense are required to sterilize the typically more complex knee surgery tools, so relatively higher sterilization costs should be assigned to knee replacements.

When costing support departments, a good guideline is the “rule of 1.” Support functions that have only one employee can be treated as a fixed cost; they can be either not allocated at all or allocated using a simplistic method, as is currently done. But departments that have more than one person or more than one unit of any resource represent variable costs. The workload of these departments has expanded because of increased demand for the services and outputs they provide. Their costs should and can be assigned on the basis of the patient processes that create demand for their services.

Project teams tasked with estimating the cost to supply resources—the numerator of the capacity cost rate—should have expertise in finance, human resources, and information systems. They can do this work in parallel with the process mapping and time estimation (steps 3 and 4) performed by clinicians and team members with expertise in quality management and process improvement.

6. Estimate the capacity of each resource, and calculate the capacity cost rate.

Determining the practical capacity for employees—the denominator in the capacity cost rate equation—requires three time estimates, which are gathered from HR records and other sources:

- a. The total number of days that each employee actually works each year.
- b. The total number of hours per day that the employee is available for work.
- c. The average number of hours per workday used for nonpatient-related work, such as breaks, training, education, and administrative meetings.

$$\text{Monthly Practical Capacity of Resource} = \frac{a}{12} \times (b-c)$$

For physicians who divide their time among clinical, research, and education activities, we subtract time spent on research and education activities to obtain the number of hours per month that they are available for clinical work.

For equipment resources, we measure capacity by estimating the number of days per month and the number of hours per day that each piece of equipment can be used. This represents the upper limit on the capacity of the equipment. The actual capacity utilization of much health care equipment is sometimes lower because equipment capacity is supplied in large lumps. For instance, suppose a piece of equipment can do 10,000 blood tests a month. A hospital decides to buy the equipment knowing that it needs to process only 6,000 tests per month. In this case, we make an adjustment: The costing system should use the time required to perform 6,000 tests as the capacity of the resource. Otherwise, the tests actually performed on the equipment will, at best, cover only 60% of its cost. If the provider subsequently ends up using the equipment for a higher number of tests, it can adjust the capacity rate accordingly.

This treatment of capacity follows the rule of 1 and should be applied when the organization has only one unit of the equipment. Now suppose a provider has 12 facilities that each use equipment capable of performing 10,000 blood tests per month—but each facility performs only 6,000 tests per month. In that case, the capacity of each resource unit should be set at the full 10,000 tests per month, not its expected number. We want the system to signal the cost of unused capacity when a provider chooses to supply capacity at multiple locations or facilities rather than consolidating its use of expensive equipment.

In addition to the lumpiness with which capacity gets acquired, factors such as peak load demands, surge capacity, and capacity acquired for future growth should be accounted for. This applies to both equipment and personnel. (Those factors can be incorporated, but the treatment is beyond the scope of this article.)

In practice, we have found that underutilization of expensive equipment capacity is often not a conscious decision but a failure of the costing system to provide visibility into resource utilization. That problem is corrected by the TDABC approach. We describe opportunities to improve resource capacity utilization later in the article.

To calculate the resource capacity cost rate, we simply divide the resource's total cost (step 5) by its practical capacity (step 6) to obtain a rate, measured in dollars or euros per unit of time, typically an hour or a minute.

7. Calculate the total cost of patient care.

Steps 3 through 6 establish the structure and data components of the TDABC system. In the final step, the project team estimates the total cost of treating a patient by simply multiplying the capacity cost rates (including associated support costs) for each resource used in each patient process by the amounts of time the patient spent with the resource (step 4). Sum up all the costs across all the processes used during the patient's complete cycle of care to produce the total cost of care for the patient.

Opportunities to Improve Value

Our new approach actively engages physicians, clinical teams, administrative staff, and finance professionals in creating the process maps and estimating the resource costs involved in treating patients over their care cycle. This bridges the historical divide between managers and clinical teams that has often led to tensions and stalemates over cost-cutting steps. TDABC builds a common information platform that will unleash innovation based on a shared understanding of the actual processes of care. Even at our pilot site Schön Klinik, which already had an excellent departmental cost-control system, introducing TDABC revealed powerful new ways to improve its processes and restructure care delivery. Capitalizing on these value-creating opportunities—previously hidden by inadequate and siloed costing systems—is the key to solving the health care cost problem. Let's examine some of the most promising opportunities that proper costing reveals.

Eliminate unnecessary process variations and processes that don't add value.

In our pilots, we have documented significant variation in the processes, tools, equipment, and materials used by physicians performing the same service within the same unit in the same facility. For example, in total knee replacement, surgeons use different implants, surgical kits, surgeons' hoods, and supplies, thereby introducing substantial cost variation in treating patients with the same condition at the same site. The surgical unit now measures the costs and outcomes that each surgeon produces. As a result, clinical practice leaders are able to have more constructive and better informed discussions about how best to standardize care and treatment processes to reduce the costs of variability and limit the use of expensive approaches and materials that do not demonstrably lead to improved outcomes.

In addition to reducing process variations, our pilot sites have eliminated steps or entire processes that did not improve outcomes. Schön Klinik, for example, lowered costs by reducing the breadth of tests included in its common laboratory panel after learning that many of the tests did not provide new information that would lead to improvement in outcomes.

Comparing practices across different countries for the same condition also reveals major opportunities for improvement. The reimbursement for a total joint replacement care cycle in Germany and Sweden is approximately \$8,500, including all physician and technical services and excluding only outpatient rehabilitation. The comparable figure in U.S. medical centers is \$30,000 or more. Since providers in all three countries report, in aggregate, similar margins on joint replacement care, U.S. providers' costs are likely two to three times as high as those of their European counterparts. By comparing process maps and resource costs for the same medical condition across multiple sites, we can determine how much of the cost difference is attributable to variations in processes, protocols, and productivity and how much is attributable to differences in resource or supply costs such as wages and implant prices. Our initial research suggests that although inputs are more expensive in the United States, the higher cost in U.S. facilities is mainly due to lower resource productivity.

Improve resource capacity utilization.

The TDABC approach identifies how much of each resource's capacity is actually used to perform processes and treat patients versus how much is unused and idle. Managers can clearly see the quantity and cost of unused resource capacity at the level of individual physicians, nurses, technicians, pieces of equipment, administrators, or organizational units. Resource utilization data also reveal where increasing the supply of certain resources to ease bottlenecked processes would enable more timely care and serve more patients with only modestly higher expenditures.

When managers have greater visibility into areas where substantial and expensive unused capacity exists, they can identify the root causes. For example, some underutilization of expensive space, equipment, and personnel is caused by poor coordination and delays when a patient is handed off from one specialty or service to the next. Another cause of low resource utilization is having specialized equipment available just in case the need arises. Some facilities that serve patients with unpredictable and rare medical needs make a deliberate decision to carry

extra capacity. In such cases, an understanding of the actual cost of excess capacity should trigger a discussion on how best to consolidate the treatment of such patients. Much excess resource capacity, however, is due not to rare conditions or poor handoffs but to the prevailing tendency of many hospitals and clinics to provide care for almost every type of medical problem. Such fragmentation of service lines introduces costly redundancy throughout the health care system. It can also lead to inferior outcomes when providers handle a low volume of cases of each type. Accurate costing gives managers a valuable tool for consolidating patient care for low-volume procedures in fewer institutions, which would both reduce the high costs of unused capacity and improve outcomes.

Deliver the right processes at the right locations.

Many services today are delivered in over-resourced facilities or facilities designed for the most complex patient rather than the typical patient. By accurately measuring the cost of delivering the same services at different facilities, rather than using figures based on averaged direct costs and inaccurate overhead allocations, providers are able to see opportunities to perform particular services at properly resourced and lower-cost locations. Such realignment of care delivery, already under way at Children's Hospital Boston, improves the value and convenience of more routine services for both patients and caregivers while allowing tertiary facilities to concentrate their specialized resources on truly complex care.

Match clinical skills to the process.

Resource utilization can also be improved by examining whether all the processes currently performed by physicians and other skilled staff members require their level of expertise and training. The process maps developed for TDABC often reveal opportunities for appropriately skilled but lower-cost health care professionals to perform some of the processes currently performed by physicians without adversely affecting outcomes. Such substitutions would free up physicians and nurses to focus on their highest-value-added roles. (For an example from one of our pilot sites, see the sidebar "A Cancer Center Puts the New Approach to Work.")

**PILOT: A Cancer Center Puts
the New Approach to Work,**

Speed up cycle time.

000114

**by Heidi W. Albright, MHA,
and Thomas W. Feeley, MD**

The University of Texas MD Anderson Cancer Center is a National Cancer Institute–designated Comprehensive Cancer Center, located in Houston, Texas. Seeing more than 30,000 new patients every year, MD Anderson accounts for approximately 20% of cancer care within the Houston region and 1% of cancer care nationally. MD Anderson is a medical condition–focused center that provides integrated, interdisciplinary care across the care cycle.

In collaboration with Michael Porter, we embarked on a major effort to expand clinical outcome measurement, beginning with a study of 2,468 patients in the Head and Neck Center, in 2008. We created the Institute for Cancer Care Excellence in December 2008 to support this effort. In 2010, with Robert Kaplan, we launched a pilot project, also within the Head and Neck Center, to assess the feasibility of applying modern cost accounting to health care delivery.

Traditionally, at MD Anderson, we used a charge-based cost accounting system. However, we realized that its cost allocations were problematic at several levels. For a start, the drivers of cost in health care had changed but the allocation methodology had not, with the result that our costing no longer reflected reality. What’s more, MD Anderson routinely allocated more costs to services that were highly reimbursed. With impending health care reform set to shift the industry away from fee-for-

Health care providers have multiple opportunities to reduce cycle times for treating patients, which in turn will reduce demand for resource capacity. For example, reducing the time that patients have to wait will reduce demand for patient supervision and space. Speeding up cycle time also improves outcomes, both by minimizing the duration of patient uncertainty and discomfort and by reducing the risk of complications and minimizing disease progression. As providers improve their process flows and reduce redundancy, their patients will no longer have to be so “patient” as they receive a complete cycle of care.

Optimize over the full cycle of care.

Health care providers today are typically organized around specialties and services, which complicates coordination, interrupts the seamless, integrated flow of patients from one process to the next, and leads to the duplication of many processes. In the typical care delivery process, for example, patients see multiple providers in multiple locations and undergo a separate scheduling interaction, check-in, medical consultation, and diagnostic workup for each one. This wastes resources and creates delays. The TDABC model makes visible the high costs of these redundant administrative and clinical processes, motivating professionals from different departments to work together to integrate care across departments and

service reimbursement to bundled or global payments, we needed a costing system that could provide more accurate patient-level costs by medical condition.

To determine whether time-driven activity-based costing (TDABC) would provide this level of accuracy, we worked with a team of clinicians and internal financial staff members in a pilot study. The team began by developing a care delivery value chain that mapped out the full treatment of a patient. Within each segment of care—the outpatient clinic, diagnostic imaging, the operating room, inpatient care, radiation therapy, and chemotherapy administration—we created process maps that also included all the resources involved. Each segment of the process map took approximately 40 hours to complete, with a team consisting of a project manager, a project coordinator, a process mapping expert, financial staff, clinical and business managers, and staff members from each function being mapped. (See the exhibit “New-Patient Process Map” for an example.)

The new process resulted in a 16% reduction in process time, a 12% decrease in costs for technical staff, and a 67% reduction in costs for professional staff.

The project team then estimated how much time it takes to perform each task and the capacity cost of each health care provider. We validated all the process steps, time estimates, and branching points with the help of frontline health

specialties. Eliminating unnecessary administrative and clinical processes represents one of the biggest opportunities for lowering costs.

With a complete picture of the time and resources involved, providers can optimize across the entire care cycle, not just the parts. Physicians and staff may shift more of their time and resources to the front end of the care cycle—to activities such as patient education and clinical team consultations—to reduce the likelihood of patients experiencing far more costly complications and readmissions later in the cycle.

Additionally, this resource- and process-based approach gives providers visibility into valuable nonbilled events in the cycle of care. These activities—such as nurse counseling time, physician phone calls to patients, and multidisciplinary care team meetings—can often make major contributions to efficiency and favorable outcomes. Because existing systems hide these costs in overhead (see Myth #1), such important elements of care are prone to be minimized or left unmanaged.

Capturing the Payoffs

personnel who were actually performing the tasks—not just departmental managers and senior leaders.

We then estimated the per-patient cost for each process step. Initially, we examined only personnel costs because they accounted for approximately 75% of total costs at the Head and Neck Center. Because of personnel and time constraints, we used an approximate procedure on the first pass to allocate the overhead costs of support departments.

Our pilot study also sought to evaluate whether the new costing approach would allow us to measure the cost consequences of changes in care processes. We examined the process for a patient visit to our Anesthesia Assessment Center (AAC), which occurs prior to surgery. The medical director of the AAC had developed two initiatives to improve performance: (1) implementing new clinical guidelines for preoperative diagnostic testing and (2) reorganizing personnel tasks—that is, having medical assistants perform some tasks previously performed by nurses and using nurses to perform some tasks previously performed by physicians.

The project team developed process maps for the AAC before and after the performance improvements, and then applied costs from the TDABC model to each map. The modified process resulted in a 16% (11-minute) reduction in process time, a 12% decrease in costs for technical staff, and a 67% reduction in costs for professional staff (physicians and other providers). Total costs fell

“Calculating the return on investment of performance improvement has been missing from most of the quality improvement discussions in health care,” Dr. Thomas Feeley at MD Anderson told us. “When measurement does occur, the assumptions are usually gross, inaccurate, and sometimes overstated,” he added. “TDABC gave us a powerful tool to actually model the effect an improvement will have on costs.” Accurate costing allows the impact of process improvements to be readily calculated, validated, and compared.

The big payoff occurs when providers use accurate costing to translate the various value-creating opportunities into actual spending reductions. A cruel fact of life is that total costs will not actually fall unless providers issue fewer and smaller paychecks, consume less (and less expensive) space, buy fewer supplies, and retire or dispose of excess equipment. Facing revenue pressure due to lower reimbursements—particularly from government programs such as Medicare and Medicaid—providers today use a hatchet approach to cost reduction by mandating arbitrary cuts across departments. That approach jeopardizes both the quality and the supply of care. With accurate costing, providers can target their cost reductions in areas where real improvements in resource

36%, from approximately \$250 per patient (including direct and indirect costs) to \$160. Our existing costing system could not provide visibility into the cost savings from these process improvements.

To see whether the cost reductions affected outcomes, we examined day-of-surgery cancellations due to inadequate preoperative workup and found that this critical outcome of the anesthesia assessment process did not change. Thus, the more efficient and less costly process improved value.

TDABC, which we have found straightforward to implement, requires a significant time investment to develop process maps for all care areas. But this investment has yielded additional benefits by supporting process improvement opportunities and facilitating the standardization of care. Perhaps most important, the new costing approach helps us set priorities for process improvements and measure their cost impact.

We are now completing the analysis of our pilot project data and will be extending the methodology to all our other integrated cancer care units. As we merge ongoing measurement of clinical outcomes in each of our care centers with patient-level costs for a full care cycle, we will be better positioned to drive value improvement and develop bundled prices for clinical care. Through this work, we hope to provide convincing evidence of the health care value that MD Anderson's integrative cancer treatment strategy actually delivers.

utilization and process efficiencies enable providers to spend less without having to ration care or compromise its quality.

Health care organizations today, like all other firms, conduct arduous and time-consuming budgeting and capacity planning processes, often accompanied by heated arguments, power negotiations, and frustration. Such difficulties are symptomatic of inadequate costing systems and can be avoided.

When providers understand the total costs of treating patients over their complete cycle of care, they can contemplate innovative reimbursement approaches without fear of sacrificing their financial sustainability.

A TDABC budgeting process starts by predicting the volume and types of patients the provider expects. Using these forecasts combined with

Heidi W. Albright is the director of the Institute for Cancer Care Excellence at MD Anderson Cancer Center.

Thomas W. Feeley is the Helen Shafer Fly Distinguished Professor of Anesthesiology and the vice president of medical operations at MD Anderson Cancer Center.

the process maps for treating each patient condition, providers can predict the quantity of resource hours required. This can then be divided by the practical capacity of each resource type to obtain accurate estimates of the quantity of each resource needed to meet the forecasted demand. Estimated monthly expense budgets for future periods can be easily obtained by multiplying the quantity of each resource category required by the monthly cost of each

resource.

In this way, managers can make virtually all their costs "variable." They can readily see how efficiency improvements and process innovations lead to reduced spending on resources that are no longer needed. Managers also have the information they need to redeploy resources freed up as a result of process improvements. Leaders gain a tool they never had before: a way to link decisions about patient needs and treatment processes directly to resource spending.

Reinventing Reimbursement

If we are to stop the escalation of total health care costs, the level of reimbursement must be reduced. But how this is done will have profound implications for the quality and supply of health care. Across-the-board cuts in reimbursement will jeopardize the quality of care and likely lead to severe rationing. Reductions that enable the quality of care to be maintained or improved need to be informed by accurate knowledge of the total costs required to achieve the desired outcomes when treating individual patients with a given medical condition.

The current system of reimbursement is disconnected from actual costs and outcomes and discourages providers and payors from introducing more cost-effective processes for treating patients. With today's inadequate costing systems, reimbursement rates have often been based

on historical charges. That approach has introduced massive cross subsidies that reimburse some services generously and pay far below costs for others, leading to excess supply for well-reimbursed services and inadequate delivery and innovation for poorly reimbursed ones.

Accurate costing allows the impact of process improvements to be readily calculated, validated, and compared.

Adjusting only the level of reimbursement, however, will not be enough. Any true health care reform will require abandoning the current complex fee-for-service payment schedule altogether. Instead, payors should introduce value-based reimbursement, such as bundled payments, that covers the full care cycle and includes care for complications and common comorbidities. Value-based reimbursement rewards providers who deliver the best overall care at the lowest cost and who minimize complications rather than create them. The lack of accurate cost data covering the full cycle of care for a patient has been the major barrier to adopting alternative reimbursement approaches, such as bundled reimbursement, that are more aligned with value.

We believe that our proposed improvements in cost measurement, coupled with better outcome measurement, will give third-party payors the confidence to introduce reimbursement methods that better reward value, reduce perverse incentives, and encourage provider innovation. As providers start to understand the total costs of treating patients over their complete cycle of care, they will also be able to contemplate innovative reimbursement approaches without fear of sacrificing their financial sustainability. Those that deliver desired health outcomes faster and more efficiently, without unnecessary services, and with proven, simpler treatment models will not be penalized by lower revenues.***

Accurately measuring costs and outcomes is the single most powerful lever we have today for transforming the economics of health care. As health care leaders obtain more accurate and appropriate costing numbers, they can make bold and politically difficult decisions to lower costs while sustaining or improving outcomes. Dr. Jens Deerberg-Wittram, a senior executive at Schön Klinik, told us, "A good costing system tells you which areas are worth addressing and gives you

confidence to have the difficult discussions with medical professionals.” As providers and payors better understand costs, they will see numerous opportunities to achieve a true “bending of the cost curve” from within the system, not in response to top-down mandates. Accurate costing also unlocks a whole cascade of opportunities, such as process improvement, better organization of care, and new reimbursement approaches that will accelerate the pace of innovation and value creation. We are struck by the sheer size of the opportunity to reduce the cost of health care delivery with no sacrifice in outcomes. Accurate measurement of costs and outcomes is the previously hidden secret for solving the health care cost crisis.

The authors would like to acknowledge the extensive and invaluable assistance of Mary Witkowski, Dr. Caleb Stowell, and Craig Szela in the preparation of this article.

A version of this article appeared in the September 2011 issue of *Harvard Business Review*.

For Further Reading

Measuring Value and Outcomes

“What Is Value in Health Care?” by M.E. Porter, *New England Journal of Medicine*, 2010

Redefining Health Care: Creating Value-Based Competition on Results by M.E. Porter and E.O. Teisberg, Harvard Business Review Press, 2006

“A Strategy for Health Care Reform: Towards a Value-Based System” by M.E. Porter, *New England Journal of Medicine*, 2009

Time-Driven Activity-Based Costing

Time-Driven Activity-Based Costing: A Simpler and More Powerful Path to Higher Profits by R.S. Kaplan and S.R. Anderson, Harvard Business Review Press, 2007

Cost and Effect: Using Integrated Cost Systems To Drive Profitability and Performance by R.S. Kaplan and R. Cooper, Harvard Business Review Press, 1998



Robert S. Kaplan is a senior fellow and the Marvin Bower Professor of Leadership Development, Emeritus, at Harvard Business School. He is co-developer of Time-Driven Activity-Based Costing and the Balanced Scorecard.



Michael E. Porter is a University Professor based at Harvard Business School.

This article is about COSTS

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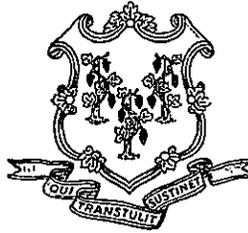
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000122

EXHIBIT F

SENATOR GAYLE SLOSSBERG

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State of Connecticut
SENATE
Fourteenth District

Chair
Education
Vice Chair
Human Services
Member
Appropriations
General Law
Regulation Review

June 17, 2016

Kimberly R. Martone
Director of Operations
CT Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Certificate of Need Application for One Additional 1.5 Tesla MRI filed by
Connecticut Orthopaedic Specialists, P.C.

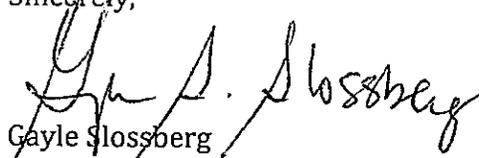
Dear Ms. Martone,

I am writing in support of the application of Connecticut Orthopaedic Specialists, P.C. ("COS") to allow them to purchase a mobile 1.5 Tesla magnetic resonance imaging unit ("MRI"). Currently, COS has two MRI units: one in their surgery center in Branford, and the other in their Hamden office. However, COS has grown over the last few years and has more than doubled the size of its practice. It is heartening to see that talented physicians in the orthopedic specialty have chosen to join COS to provide the people in south/central Connecticut and the shoreline with outstanding orthopedic services. COS is a leader in reimbursement reform and has established a number of bundled payment programs with major payers in the State. Due to the growth of its practice, COS needs an additional MRI unit in order to continue to keep the quality of care at its best.

COS has always attempted to keep all of the affiliated services surrounding their orthopedic care within their offices so that they can manage the patient's medical condition without delays, and also to keep the cost as reasonable as possible. COS does not charge facility fees. With the addition of a mobile MRI that could service the offices COS has had for years in Orange and Essex, they can offer an MRI service where the physicians will have the results overnight, and the radiologist who reads the scan will be part of the COS practice. COS will not accept referrals for MRIs from outside the COS practice.

I strongly urge the Office of Health Care Access to approve this application

Sincerely,


Gayle Slossberg
State Senator, 14th District



Selectmen's Office

www.essexct.gov

Norman M. Needleman, First Selectman

Email: nneedleman@essexct.gov

Board of Selectmen:

Stacia R. Libby

Bruce M. Glowac

Essex Town Hall

29 West Avenue

Essex, Connecticut 06426

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June 15, 2016

Kimberly R. Martone
Director of Operations
CT Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134-0308

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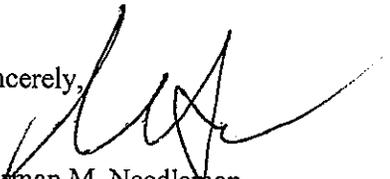
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I am told that COS is a leader in reimbursement reform and has established a number of bundled payment programs with major payers in the State. Due to the growth of its practice, especially in the Essex region, COS needs an additional MRI unit in order to continue to keep the quality of care at its best and to allow the members of our community to receive diagnostic services close to home. There are no other MRI units in our town and the MRI service in Madison, CT is no longer available to our residents.

I strongly urge the Office of Health Care Access to approve this application, which I believe will be a great enhancement to the healthcare available to residents of Essex.

Sincerely,


Norman M. Needleman
First Selectman

000125





State of Connecticut
HOUSE OF REPRESENTATIVES
STATE CAPITOL
HARTFORD, CONNECTICUT 06106-1591

REPRESENTATIVE PHILIP MILLER
THIRTY-SIXTH ASSEMBLY DISTRICT

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CO CHAIR
PLANNING & DEVELOPMENT

MEMBER
ENVIRONMENT COMMITTEE
LEGISLATIVE PROGRAM REVIEW & INVESTIGATIONS
COMMITTEE

Kimberly R. Martone
Director of Operations
CT Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS #13HCA
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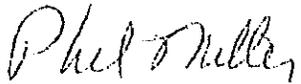
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Finding ways to lower the cost of healthcare has been a strongly debated topic not only in Hartford but on a national level. Connecticut Orthopaedic Specialists has established itself as a leader in CT not only in the quality of care it provides but also through innovative payment reform strategies including a number of bundled payment programs with major payers in the State. In order for COS to be able to take on reimbursement reform, manage risk, and provide high quality accessible care, they need an additional MRI unit to service the greater Essex community.

I strongly support the application for a mobile MRI that could service the offices COS has had for years in Orange and Essex.

Sincerely,

A handwritten signature in cursive script that reads "Philip Miller".

State Representative Philip Miller

000127



State of Connecticut
HOUSE OF REPRESENTATIVES
STATE CAPITOL
HARTFORD, CONNECTICUT 06106-1591

REPRESENTATIVE PHILIP MILLER
THIRTY-SIXTH ASSEMBLY DISTRICT

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CO CHAIR
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Kimberly R. Martone
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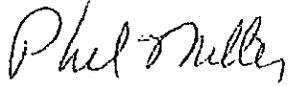
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I strongly support the application for a mobile MRI that could service the offices COS has had for years in Orange and Essex.

Sincerely,

A handwritten signature in cursive script that reads "Philip Miller".

State Representative Philip Miller

000129



July 11, 2016

Kimberly R. Martone
Director of Operations
CT Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Certificate of Need Application for One Additional 1.5 Tesla MRI filed by
Connecticut Orthopaedic Specialists, P.C.

Dear Ms. Martone,

I am writing in support of the application of Connecticut Orthopaedic Specialists, P.C. ("COS") to purchase a mobile 1.5 Tesla magnetic resonance imaging unit ("MRI"). COS providers' are part of the Workers' Compensation Trust's managed care plan and deliver exceptional care to our injured workers in the south/central and shoreline communities. With the utilization of COS' MRI units in Branford and Hamden, we are able to schedule an MRI scan shortly after the provider has requested it, thus resulting in a faster diagnosis and treatment plan. By having on-site MRI, it allows for the results to be delivered to us much sooner due to their in-house radiologist who interprets the scan and reports back to the provider through their EMR. With the expedited service that COS offers, our injured workers are able to begin their recovery process without delays.

It is my understanding from COS that due to the growth of its practice and the demand on their current MRI units, COS is in need of an additional MRI unit in order to continue to keep the quality of care that they provide our injured workers at its best. Therefore, I am in support of COS obtaining a mobile MRI unit to service our clients in the Essex and Orange geographic regions to continue with the continuum care model that COS executes so well.

Sincerely,

Brian S. Downs
Vice President, Quality & Provider Relations

000130

EXHIBIT G

000131



Connecticut Orthopaedic Specialists

AND OUR DIVISIONS



The Orthopaedic Group OrthopedicHealth



Center For Orthopaedics

SHORELINE

ORTHOPEDICS & SPORTS MEDICINE

COS MRI Protocols / Guidelines

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Connecticut Orthopaedic Specialists

AND OUR DIVISIONS

The Orthopaedic Group

OrthopedicHealth



Center For Orthopaedics

SHORELINE

ORTHOPEDICS & SPORTS MEDICINE

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Connecticut Orthopaedic Specialists

AND OUR DIVISIONS



The Orthopaedic Group

OrthopedicHealth



Center For Orthopaedics

SHORELINE

ORTHOPEDICS & SPORTS MEDICINE

PURPOSE:

- Establish the policies and procedures to maintain safe clinical practice involving magnetic resonance imaging (MRI) devices at COS facilities.
- Implement an MRI program that models the safety recommendations structured by the American College of Radiology (ACR) for safe practices.
- Perform high quality imaging under the discretion of the medical director

RESPONSIBILITIES OF MRI MANAGER:

- Manage the maintenance of the MRI equipment by working with qualified vendors to perform frequent assessments including alignment, calibration and repairs
- Review credentialing of MRI technicians upon hire and annually for purposes of verifying licences and training requirements
- Educate all individuals who assist with patient care in the vicinity of MRI unit on the use of equipment, their work space and the potential health hazards associated with specific zones while MRI testing is in progress
- Perform frequent checks of the coils for wear and tear

TRAINING/QUALIFICATIONS

- MRI safety training is required for MRI technicians and non-technical staff (dependent of their job description) to be informed of the potential work hazards in our MRI suites
- Technicians and non-technical staff are required to complete an MRI safety training refresher course annually through the practice's intranet site. The results are documented and kept on file for the duration of their employment plus three years thereafter.
- Training documentation must be approved by the Radiology Safety Officer

MEDICAL DIRECTOR

- Joseph Gagliardi, MD



MRI SUITE SAFETY INFORMATION

STATIC MAGNETIC FIELD:

The most common breaches of MRI safety occur due to an object being attracted to the Static Magnetic Field. Any individual may be struck, injured or trapped against the magnet by a magnetically attracted object. If such an instance were to occur the equipment may be damaged due to the collision of the magnetically charged object and the magnet; as the object with attract to the magnet at a high velocity.

- Field Strength
 - The strength of the static field is regulated by the federal government with 3.0 Tesla magnets being maximum strength for clinical use. Connecticut Orthopaedic Specialists' MRI units meet the federal requirement with the use 1.5 Tesla magnets
- Projectile Effect
 - Items that are ferromagnetic have the potential of becoming projectiles when brought into the magnetic field.
 - Projectiles have the potential of causing serious injury, including death to anyone who may be in the path of the object as it accelerates toward the magnet. Projectiles may cause an individual to be pinned to the magnet, if the magnetically charged object is attached to the individual. Equipment may be irreparably damaged by a projectile in such an event.



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RADIO FREQUENCY (RF) ELECTROMAGNETIC FIELDS

Safety risks from RF include potential tissue heating and burns to the patients. RF may damage electronic or implanted devices. Equipment that is not RF shielded may be damaged or may cause spurious signals when operated in the magnetic field. Conducting materials within the RF field may result in a concentration of electrical currents sufficient to cause excessive heating and tissue damage. Therefore, all conducting material not in use should be removed from the magnet bore.

Cables, wires and other accessories should be inspected regularly by the MRI Technicians to ensure insulation, connectors and other components are intact and functioning safely. Any malfunctioning or broken equipment should be reported to the MRI Supervisor.

LIQUID HELIUM AND LIQUID NITROGEN

In their liquid state, helium and nitrogen are extremely cold and will freeze human tissue. Only authorized persons should fill liquid nitrogen and liquid helium containers. Injuries caused by freezing must be washed with water and treated as burns. The ventilation should be running in the examination room and only non-ferrous containers should be brought into the magnetic area.

When they evaporate, helium and nitrogen form a cold mist. Helium rises and nitrogen descends to the ground level. While these gases are odorless, non flammable, and non-poisonous, they pose a risk of suffocation because they dilute the oxygen in the air. Always keep the ventilation running in the examination room. The quench pipe will prevent evaporation of nitrogen and helium into the magnet room and release it into the air outside the building.



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ZONES OF THE MRI DEPARTMENT

- **ZONE I**
 - Open to general public access.
 - This is generally the reception and waiting area for the MRI suites.
 - Purpose of this zone is to channel patients to the prescreening area (Zone II)
- **ZONE II**
 - This is the first interaction site for the patients, visitors, and others with the technical staff in the MRI suite,
 - The purpose of this zone is to restrict further public access to the site, provide direct supervision of patients and visitors by the technical staff, and provide an opportunity to prescreen all patients and visitors.
 - All ferromagnetic objects must be collected and secured within Zone II.
- **ZONE III**
 - Zone III is the entry zone to the MRI scanning room.
 - Without exception, only the certified technical staff, MRI desk staff, students, and COS doctors should be allowed free access between Zones III and IV.
 - All technical staff must be prescreened upon employment prior to entering Zone III to make sure no unscreened individuals are allowed access to Zone IV.
 - Doors are labeled and locked to prevent access by unscreened individuals.
- **ZONE IV**
 - Only those personnel required so that the patient can complete the exam will be allowed in the MRI scanning room during the procedure. Family members should remain in the waiting area unless the patient requires their presence for exam completion.
 - Code red situations (FIRE) will require the use of MRI-safe fire extinguishers and restrictions of first responders from Zone IV, until MRI safe conditions can be established or first responders verified as MRI safe.
 - In Code Red (Fire) situations, first responders **do not** have free access to either Zone III or IV
 - The entrance to this room is visually marked by signage on the normally closed room door indicating Authorized Personnel Only and entrance is restricted.

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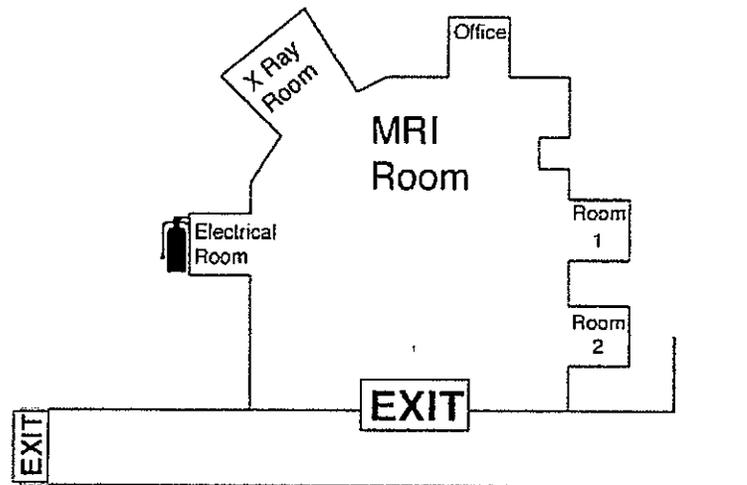
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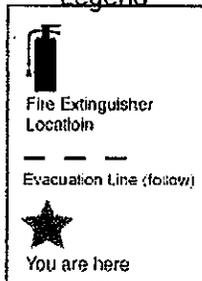
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Legend



EQUIPMENT SCREENING

All equipment used for MRI scans, must be tested for MRI safety BEFORE entering the fringe field. Individuals are cautioned to NEVER take equipment into the fringe field or into the magnet room without prior testing for magnetic attraction.



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MRI UNIT EMERGENCY PROCEDURES

- **Emergency Stop**
 - If there is an emergency such as an equipment failure that could cause injury; sparking of equipment or a fire, the scanner operator should immediately perform an emergency stop and report faulty equipment to the MRI Supervisor.

- **Magnet Emergency- quench**
 - If it is necessary to quench the magnetic field immediately (e.g. in case of fire, or a person pinned to a magnet), push the emergency magnet shut-off switch located on the magnet safety panel. Pushing the emergency switch quenches the magnet and causes the field to collapse within 10 seconds; this should only be done in a severe emergency.
 - If the door into the MRI magnet room is unable to be opened, use the specialized hammer on the window ledge to break the window.
 - Report the quench immediately to the MRI Supervisor.

- **Response to leaks of liquid helium and liquid**
 - If the door into the MRI magnet room is unable to be opened, use the specialized hammer on the window ledge to break the window.
 - Remove all jewelry from hands and wrists.
 - If skin comes in contact with cryogen, run the affected area under lukewarm water for 15 minutes DO NOT rub the affected area.
 - If injured, notify the MRI supervisor as soon as possible.
 - In the case of someone severely burned from spill , call **911**



RESPONSE TO A FIRE IN MRI

Due to the high magnetic field, fighting fires in a suite with an MRI unit pose an additional hazard. The following procedures should be followed in the event of a fire in order to prevent additional hazards to the individual, suite or facility.

- **PART A**

- **If you discover a fire, follow this order of response:**
 - Rescue
 - Alert
 - Contain
 - Extinguish

- **PART B**

- **In trying to extinguish or contain the fire, do not jeopardize your own safety.**
Do the following:
 - Disconnect electrical power to the MRI system by pressing the emergency "off" buttons.
 - Use only a non-magnetic extinguisher found in the mechanical room
 - If the fire is not extinguished after emptying the available extinguisher, or if your safety is endangered remove the magnetic field by pressing the "quench" button.
 - Screen all personnel, including firefighters, for entry to the magnetic field area.

- **PART C**

- **If a fire breaks out in the computer room:**
 - Disconnect electrical power by pressing the emergency "off" buttons.
 - If the fire is not extinguished after you have emptied the fire extinguisher, or if personnel are endangered, evacuate the room and call 911.



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DISASTER AND FIRE EVACUATION FROM BUILDING

In the event of a disaster all employees of the **Branford MRI location** are to follow these procedures:

- 1) Call 911 if required
- 2) Alert all employees and patients in the facility and escort them to the nearest appropriate exit
- 3) Check examination rooms, restrooms and offices to ensure all persons are accounted for
- 4) All employees and patients should evacuate through the same exit if possible via use of stairs if not on the ground level as use of elevators are prohibited during an emergency evacuation
- 5) Once evacuated from the building all employees and patients are to gather in the front of the building parking lot closest to North Main Street (between the Surgical Center and OrthoNOW)
(unless otherwise indicated)
- 6) Supervisor will have a copy of the current day's clinical schedule to confirm attendance once evacuated.
- 7) Once everyone is deemed safe from danger call the Operations Officer for an appropriate plan of action.

In the event of a disaster all employees of the **Hamden MRI location** are to follow these procedures:

- Follow steps 1-4 as described above
- 5) Once evacuated from the building all employees and patients are to gather in parking lot behind MRI, halfway to back of lot. (unless otherwise indicated)
- Complete steps 6-7 as described above

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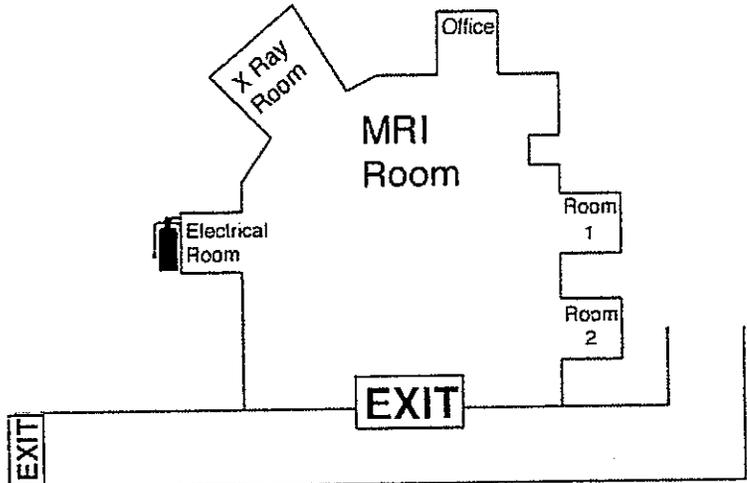
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Fire Extinguisher
Location


Evacuation Line (follow)


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MRI SAFETY SCREENING

Each person must be checked for safety or pre screened prior to entering the magnetic environment of the scanner room. An important aspect of protecting people from MRI system-related accidents and injuries involves an understanding of the risks associated with the various implants, devices, and accessories which may be present within or adjacent to the person.

• **Employees**

- All individuals, including clinical, employees, and students, who work within the magnetic environment, must be trained according to COS policy and screened for personal safety prior to entering the magnetic field.
- In addition, individuals who have the responsibility to screen patients must complete the MRI Safety Training program.
- Any individual who has a need to enter the magnet room (I.E. facility maintenance, engineers, site visitors) must be screened on a case by case basis.

• **Patients**

- Preliminary screening of patients for MRI procedures should take place during the ordering doctor's visit as an order is placed.
- A second screening takes place during the scheduling process. Such screening helps to prevent scheduling of patients who may be at risk for safe MR imaging.
- Upon arrival, it is **mandatory** for every MRI patient (even patient who have had a previous MRI) to undergo comprehensive screening in preparation for the MRI study prior to entering Zone IV.
- Family members of patients whose presence is required for exam completions are held to the same screening requirements as patients.
- Pregnancy
 - Women who are or may be pregnant may be scanned by MRI after determining that the medical benefits outweigh any possible minimal risk to the fetus by referring physician and radiologist and are required to sign a waiver.

• **Claustrophobia Screening**

- Statistics indicate that about 10% -20% of the general population is claustrophobic to some degree. By using prism glasses, lavender scented tablets and gentle breathing instructions, most patients can continue with the exam.
- If the patient does not complete the exam, the ordering doctor is contacted to decide if medication will be ordered or the patient will have an Open MRI.



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- **Thermal Heating and Burns**

- Dental hardware

- Most dental hardware is generally safe in the MRI environment although some orthodontic components may be ferromagnetic.

- Tattoos

- RF heating of tattooed tissue has been reported especially with the use of iron oxide containing inks. The patient should be informed of the potential for heating and burns and instructed to alert the technologist immediately if warming occurs.

- Transdermal Medicated Patches

- These patches contain a metallic layer which has been reported to cause heating of tissue during scanning and producing a burn on the patient. It is essential that any patient wearing a transdermal patch that has a metallic component be identified during the pre-screening process, prior to undergoing MRI.

- Coils

- Coils are the devices that transmit and receive the RF signals and can be produced in a variety of configurations. The MRI Technician must have some basic knowledge of coil technology to properly conduct MRI scans.

Safety issues can occur as follows:

- Transmitting RF energy through a receive-only coil may damage or ruin the device
- Transmitting more RF power than the coil was designed to accommodate, may damage or ruin the device.
- Twisting, looping or crossing cables may cause current to be induced, resulting in damaging the coil, abnormal heating or potential arcing
- Keep the cables off the patient and run them over blankets whenever possible
- To avoid burns or peripheral nerve stimulation, a minimum distance of 5mm should be maintained between the patient's body and the wall of the scanner tunnel. MR pads or cotton sheets available in the MR scan can be used to assure the distance is maintained,



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- **Implants and devices**

- Implants and devices are rapidly evolving and must be thoroughly investigated if potential patients or individuals who will enter the magnetic environment indicate their presence. If the individual knows or has documentation as to the specific manufacturer and type of device, then the following steps are implemented:

- Look up the item by manufacturer in the current Reference Manual for Magnetic Resonance Safety, Implants, and Devices by Frank G. Shellock, PhD. Or on the web site : <http://www.mrisafety.com>

- If the device or object is listed, but has not been tested at the field strength patient is subjected to, then contact the manufacturer for the following information and written documentation:

- Have the manufacturer fax certified document that states the device is MRI safe and at which field strength and conditions it is safe.
- The document should also include the FDA date stamp that verifies the device is MRI safe.

- **Orbit Wavier**

- If a patient admits to having had metal in their eye or past history of working with metal, an orbits test will be ordered. An orbits test will be able to rule out if the patient has any metal fragments in their eyes as a preventative measure to protect the patient against harm during MR testing; due to the strong magnetic fields used for imaging.

HEARING PROTECTION POLICY

Acoustic levels in the MRI scan room may exceed 99dBA. Hearing protection is required for all people in the magnet room during a scan to prevent hearing impairment. Staff must adhere to the following rules:

- All patients will be provided hearing protection.
- All patients will either receive ear plugs or head phones to protect their hearing.
- All patients' family members that go into the MRI scan room will be required to wear ear plugs.



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LASER LIGHT LOCALIZER HAZARDS

A laser is available for land marking the patient's position in the 1.5 GE scanners. Patients should be instructed to keep their eyes closed while the laser light is turned on to avoid eye injury. If the laser light appears as a spot, rather than as crosshairs, it should be reported to the MRI supervisor.

COS POLICY FOR PREGNANT MRI EMPLOYEES

There are no nationally uniform or accepted guidelines for the pregnant technologist working with MRI units. An abstract was presented by Dr. Kanal in 1993, "Survey of reproductive health among female MRI workers" evaluating potential risks. ACR published, "ACR Guidance Document for Safe MR Practice 2007." Based on the findings presented by Dr. Kanal the following is the recommendation from ACR's document for Safe MR Practice.

Pregnancy-Related Issues

Health care practitioner pregnancies

Pregnant health care practitioners are permitted to work in and around the MR environment throughout all stages of their pregnancy. Acceptable activities include, but are not limited to, positioning patients, scanning, archiving, injecting contrast material, and entering the MR scan room in response to an emergency. Although permitted to work in and around the MR environment, pregnant health care practitioners are requested not to remain within the MR scanner bore or Zone IV during actual data acquisition or scanning.



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PATIENT PREGNANCY POLICY

- Women who are or may be pregnant may be scanned by MRI after determining that the medical benefits outweigh any possible minimal risk to the fetus by referring physician and radiologist and are required to sign a waiver.

PATIENT PREGNANCY WAIVER

- Patients that identify that they are pregnant are presented with a document, of which they are to consent to the terms prior to receiving the MR scan.
- Pregnant patients are required to consent to the following terms:
 - There is no national accepted guideline for M.R.I. scanning of a pregnant woman. The safety of the General Electric 1.5 Tesla (MRI) system when used during pregnancy has not been established and it is strongly recommended by the manufacturer that scanning should not be performed during the first trimester of pregnancy due to possible health effects to the fetus. Considering that there are no official guidelines for pregnant women the decision to have a M.R.I. examination is at the discretion of the patient. If you wish to proceed with the MRI examination please be aware that you are willing to accept full responsibility for any complications which may affect your unborn child. I have read the above criteria pertaining to my pregnancy and the health of my unborn child and I wish to proceed with the MRI.

PATIENT MONITORING

Monitoring during an MRI examination is indicated whenever a patient requires observation of vital physiologic parameters due to an underlying health problem or is unable to respond or alert the MRI technologist regarding pain, respiratory problem, cardiac distress, or difficulty that may arise during the examination. The technologist will provide verbal communication throughout the examination.

The scanners are also equipped with a squeeze ball that allows the patient to set off an audible alarm to attract the operator's attention. The squeeze ball is made available to the patients at the conclusion of positioning.

In 1992, the Safety Committee of the Society of Magnetic Resonance Imaging published guidelines and recommendations concerning the monitoring of patients during MRI procedures. This information indicates that all patients undergoing MRI procedures should, at the very least, be visually and/or verbally monitored; for which Connecticut Orthopaedic Specialists meets the requirement.



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Severe injuries and fatalities have occurred in association with MRI procedures. These may have been prevented with the proper use of monitoring equipment and devices. Importantly, guidelines issued by the Joint Commission of Accreditation of Healthcare Organizations (JCAHO) indicate that patients receiving sedatives or anesthetics require monitoring during administration and recovery from these medications. Connecticut Orthopaedic Specialists currently do not use sedation/anesthesia.

- **Patients that require extra monitoring and support during MRI procedures are:**
 - Physically or mentally unstable patients
 - Patients with compromised physiologic functions
 - Patients who are unable to communicate
 - Pediatric patients
 - Patients who may have a reaction to an MRI contrast agent
 - Critically ill or high risk patients

*Connecticut Orthopaedic Specialists does not scan patients that require additional monitoring devices (i.e. EKG, ECG, blood pressure, oxygen, neonatal, sedated, anesthetized etc.)

CONTRAST ADMINISTRATION AND REACTIONS

Gadolinium chelates have been approved for parenteral use since the late 1980's. Although these agents can be differentiated on the basis of stability, viscosity, and osmolality, they can not be differentiated on the basis of efficacy. Gadolinium chelates are extremely well tolerated in the vast majority of patients that are injected. Acute adverse reactions are encountered with a lower frequency than is observed after administration of iodinated contrast media.

The frequency of all acute reactions of all acute events after an injection of 0.1 or 0.2 mmol/kg of gadolinium chelate ranges from 0.07% to 2.4%. The vast majority of reactions are mild, including coldness at the injection site, nausea with or without vomiting, headache, warmth, or pain at the injection site, paresthesias, dizziness, itching. Reactions resembling an "allergic" response are very unusual and vary in frequency. A rash, hives, or urticaria are the most frequent of this group, and very rarely there may be bronchospasm. Severe, life threatening anaphylactoid or nonallergic reactions are exceedingly rare (0.001% to 0.01%). Fatal reactions to gadolinium chelate agents occur but are extremely rare.

- **Patients with a higher possibility of a reaction**
 - Persons with asthma



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- Various allergies to medications or foods
- Persons with reports of adverse reactions to gadolinium in the past
- Persons with reports of allergic-like reactions to iodinated contrast media

TREATMENT OF ACUTE ADVERSE REACTIONS

It is imperative that personnel are trained in recognizing and handling reactions with medications and equipment needed for treatment on site if applicable.

Patients should be taken out of the imaging room immediately and away from the magnet so that none of the resuscitative equipment becomes a magnetic hazard.

STORAGE AND DISPENSING MEDICATION POLICY

The COS MRI department does not prescribe or dispense medication to patients scheduled for diagnostic testing.

The organization evaluates its contrast management system by maintaining adequate contrast supply. The Lot number and expiration dates are documented for all patients receiving contrast injections. The staff technologist is responsible to check and log expiration dates monthly and notify the manager of any supplies that are expired.

Supply is rotated when a new supply is received.

All contrast reactions are reported to the manufacturer and an incident report is filed for the patient's who experience a contrast reaction.

Multi-dose medications or contrast used for more than one patients are dated when they are first opened and discarded within 28 days after opening or the manufacturer's recommendations whichever comes first. Medications will be labeled with the date of expiration.

All medication and contrast material is maintained in a secured location.

In the event of a contrast reaction, the Radiologist is the sole administrator of emergency drugs used to treat the reaction.

These drugs are stored locked and the key returned to the lock box at the end of the shift and when the exam room is not staffed. These drugs are monitored for expiration by the assigned technologist. During hours of operation these drugs are readily available.



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MEDICATION DISPOSAL

Medication's expiration dates are checked and logged monthly by the staff technologist. Expired drugs are disposed according to state and federal guidelines.

Recalled medications will be removed from the locked storage area and disposed of according to state and federal guidelines.

MEDICAL EMERGENCY PROCEDURES

- **Written emergency procedures**
 - Written emergency procedures should be made available in the areas where MRI devices are used.
 - All MRI users shall familiarize themselves with these emergency procedures.
- **Medical Attention**
 - MRI Technical Staff shall immediately seek appropriate medical attention for any individual injured within the MRI environment.
 - The emergency team must report outside the appropriate MRI scanner room to begin treatment for the patient.
 - Crash carts and other emergency equipment containing ferromagnetic material **must not** be brought into the scanning room.

OSHA TRAINING

- Training is provided at the time of initial assignment to tasks where occupational exposure to blood and OPIM may occur. Training is also conducted annually thereafter. Training is provided during work hours and at no cost to employees.
- Training includes but is not limited to:
 - An accessible copy of the Bloodborne Pathogen Standard
 - An explanation of the epidemiology and symptoms of bloodborne diseases
 - Modes of transmission of bloodborne pathogens
 - Explanation of COS' bloodborne pathogen exposure plan, where it is located, and how a copy can be obtained.
 - How to recognize tasks which may result in exposure to blood and OPIM
 - An explanation of COS' engineering controls, work practice controls and PPE
 - The type of PPE available
 - How to select appropriate PPE and the minimum requirements for various tasks



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- How to properly dispose of PPE which is soiled and/or contaminated
- Information on the hepatitis B vaccination including benefits, efficacy, etc. and that it is offered free of charge
- Who to contact in case of an emergency involving exposure to blood or OPIM
- What to do in the case of an exposure
- Information on post exposure evaluation and follow-up treatment, which is available at no charge to employees
- Explanation of biohazard symbols
- How to handle biomedical waste generated in the office

REPORTING REQUIREMENTS - SAFETY

Mandatory MRI safety training is required for individuals who work in the magnetic environment. Any event or occurrences that may compromise the safety of the individual or patients in or near the magnetic environment need to be reported and addressed by the MRI supervisor and Safety Officer.

- **Accidents, Injuries and Incidents**
 - Any accidents causing injury to an individual or patient must be reported to the MRI Supervisor and Safety Officer.
- **Equipment Damage or Failure**
 - Malfunctions of equipment due to breakage or failure may present a safety risk to individuals and patients. Damage or failure of equipment needs to be addressed immediately so that repairs or replacements can be made, Equipment problems should be reported to the MRI Supervisor as soon as reasonably possible.
- **Notification of injury or death**
 - Any COS employee or student who becomes aware of an incident resulting in the injury or death of an individual caused by an MRI device shall immediately notify the MRI Supervisor and Safety Officer.
- **Notification of near misses**
 - Any COS employee or student who becomes aware of an event that could have resulted in the injury or death of an individual caused by an MRI device shall immediately notify the MRI Supervisor and Safety Officer within 24 hours of becoming aware of the event.



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Consent for Intra-Articular Joint Injection

Your doctor has ordered an MRI arthrogram for you. The arthrogram requires an injection of gadolinium and nonionic iodine containing contrast agent into your joint space. The contrast agent or contrast materials stand out on the MRI images and help the radiologist interpret the examination.

The contrast media is given to you through a small needle placed in the joint space. Normally, a contrast material is safe. Any injection, however, carries a slight risk of harm, including an infection. Reactions are possible with any contrast agent. Approximately 95% of adverse reactions are mild to moderate in degree and nausea, warmth, and rash.

Certain patients are at higher risk for experiencing a reaction to the contrast material. Please check each medical condition that applies to you:

- _____ History of adverse reaction to previous injection of contrast media
- _____ History of asthma
- _____ History of allergies to:
- _____ History of diabetes
- _____ History of heart disease
- _____ History of renal disease or failure

If NONE of the above conditions apply to you, initial here: _____

If you have any questions, please ask the x-ray technologist or the attending radiologist.

I have read the above information, have had my questions answered, and consent to the arthrogram examination of my _____. I am satisfied that the general purpose, potential benefits, and reasonably foreseeable problems and complications of this procedure have been discussed with me. I agree that in the event of any unforeseen condition arising during the course of the procedure, my physician will do whatever he/she deems medically appropriate.

I have read and understand the contents of this questionnaire and verify that my answers are accurate to the best of my knowledge.

Patient Name: _____ Signature: _____
 Relationship to Patient: _____ Date: _____
 Radiologist Signature: _____ Witness: _____

Radiographer Use Only:

Injectable: _____ Lot#: _____ Exp Date: _____

Addendum A

000151



BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN

The purpose of this standard is to reduce, eliminate or minimize employee bloodborne pathogen exposure. Connecticut Orthopaedic Specialists (COS) is committed to providing a safe and healthful work environment. Therefore, Connecticut Orthopaedic Specialists has created this Bloodborne Pathogens Exposure Policy to inform our employees of prevention methods and how to respond to an event in accordance to OSHA standards.

1. Those who are at risk of exposure are employees who work in the following departments:

- Clinic
- Physical/Occupational Therapy
- Radiology
- Ambulatory Surgical Center

2. Per OSHA all employees that work in the above departments have the opportunity to receive hepatitis B vaccinations, and, if necessary, post-exposure evaluation and follow-up. All of these are provided at no cost to the employee.

3. All employees will be notified that this Bloodborne Pathogens Exposure Control Plan is made available to all employees at the time of hire, readily available on the intranet and available via paper at the time of request.

4. Connecticut Orthopaedic Specialists bloodborne pathogens control plan is required to be adhered to while within the confines of COS' operating facilities including but not limited to the divisions within.

This standard was developed primarily to prevent occupational exposure to HBV and HIV. It applies to all work procedures in our practice where employees may be exposed to blood or other potentially infectious materials (OPIM) during the day-to-day execution of their duties.

Connecticut Orthopaedic Specialist's OSHA Compliance Officer and Health and Safety Committee must review and update COS' Bloodborne Pathogens Exposure Control Plan at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure. The review and update of the plan will address:

1. Changes in technology that eliminate or reduce exposure to bloodborne pathogens; and
2. Annual consideration and implementation of appropriate and commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.
3. Input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation and selection of engineering and work practice controls

OCCUPATIONAL EXPOSURE DETERMINATION

Occupational Exposure is defined by OSHA as any reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or other potentially infectious materials that could result from the performance of an employee's duties. Incidental exposures, which are neither reasonable nor routinely expected, are excluded. Departmental classifications at COS which are at risk of exposure to blood and/or OPIM are listed on page 1 of this bloodborne pathogen control plan. The classification of departments will determine whether or not an employee is at risk of exposure to bloodborne pathogens and therefore will need special protections while performing their duties.

PROTECTION AGAINST BLOODBORNE DISEASES IN THE HEALTHCARE ENVIRONMENT

Hepatitis B, hepatitis C and HIV are serious diseases. It is important for all employees to understand and follow COS' Bloodborne Pathogens Exposure Control Plan. Following the guidelines in this plan will reduce the likelihood of occupational exposure incidents. All employees at risk of exposure are offered to receive the hepatitis B vaccination, which is available to them at no charge within 10 working days of their hire. COS sees this as an effective means of preventing the disease.

All employees are encouraged to report all concerns regarding safety and health to your Health and Safety Site Representative or your OSHA Compliance Officer. It is important that you periodically re-evaluate your Bloodborne Exposure Control Plan to take into consideration new procedures; new technology and new products that will help prevent bloodborne exposure incidents.

All employees who work in a department at risk of exposure to blood and other potentially infectious materials must be trained on COS' Bloodborne Exposure Control Plan to educate themselves on the steps they must take to prevent transmission of bloodborne diseases. This training includes information on the following bloodborne diseases:

HEPATITIS B VIRUS (HBV) INFECTION

Epidemiology

Many healthcare workers exposed to blood have a high level of serum HBV (hepatitis B virus) markers indicating a previous infection. The level is several times higher than the general public and higher than that of healthcare workers who are not exposed to blood or who do not handle needles.

Symptoms

Hepatitis B symptoms can be divided into three basic groups. One third of the infected individuals have no symptoms. Another third may have mild cases exhibiting flu-like symptoms and are not usually diagnosed as having hepatitis. The remaining third may have severe symptoms such as jaundice, dark urine, nausea, abdominal pains, extreme fatigue and anorexia. There will sometimes be joint pains, fever and a rash. The virus destroys liver cells and individuals infected with hepatitis are at risk of liver cancer, cirrhosis and chronic liver disease.

Modes of Transmission

Hepatitis B is spread by contact with blood and other potentially infectious materials (OPIM). Exposure can result from any contact with blood or OPIM by non-intact skin. For example, chapped hands, cuts and any type of lesion can provide a route of entry for the virus. Direct contact with a contaminated source patient is not the only mode of transmission. Healthcare workers should be aware that transmission could occur through contact with work surfaces and other objects in the workplace that may have become contaminated with blood or OPIM.

Injuries from contaminated needles or other sharp instruments or devices are the primary modes of occupational transmission in the healthcare environment.

Hepatitis B Vaccination

Connecticut Orthopaedic Specialists follows current recommendations for the hepatitis B vaccination based on information available from the Centers for Disease Control and Prevention (the CDC). The vaccinations are given in the deltoid muscle in 3 intramuscular doses over a 6-month period. The vaccine produces protective antibodies in approximately 85-97% of healthy adults. Protection is considered to be lifelong. The antibody level may fall below detectable levels over several years but when these individuals are exposed to the hepatitis B virus (HBV), they develop a rapid antibody response and do not become ill or develop the HBV carrier state. Therefore, the CDC does not recommend booster doses at this time. If booster doses are required by future CDC recommendations, you should make them available to your at-risk employees.

Per current CDC recommendations, the initial 3-dose series must be followed by a test for the antibody to the hepatitis B surface antigen. This test (titer check) is best performed 1 to 2 months after the third dose of the vaccine. This is the *only way* that an individual can be sure that he or she seroconverted. Non-responders must be vaccinated with a second 3-dose series and retested.

Policy for Hepatitis B vaccinations

Connecticut Orthopaedic Specialists employees who are at risk of occupational exposure should be identified by their departmental classification. Hepatitis B vaccinations are offered at the time of initial employment at COS and all "at-risk" employees are actively encouraged to take advantage of the opportunity. The hepatitis B vaccine is offered at no charge to our employees within 10 days of the date of hire. Employees are allowed to conduct patient care procedures during the time it takes to complete the series. COS follows the current CDC guidelines and offers employees antibody tests after the third dose followed by revaccination for all non-responders. These procedures are available at no charge to COS employees.

COS employees who elect not to receive the hepatitis B vaccination series must sign a copy of COS' Declination Form (Informed Refusal of the Hepatitis B Vaccination). If a COS employee changes their mind during their term of employment with COS, the vaccine is available to you at no charge.

HEPATITIS C VIRUS (HCV) INFECTION

Epidemiology

At this time, it is estimated that approximately 4 million American adults are infected with hepatitis C. (This is approximately 1 out of 50.) A majority of the infections resulted from blood transfusions or dialysis treatments prior to 1992 since the blood supply was not routinely screened for this virus. The disease can also be contracted through bloodborne exposure incidents in healthcare environments although it is less likely than hepatitis B to be transmitted this way. In the United States, hepatitis C is the single leading cause for liver transplants.

Symptoms

Hepatitis C is called the "silent killer" because a person can be infected with the disease and either have no symptoms or mild flu-like symptoms, which often go undiagnosed. It is often the case that hepatitis C is not diagnosed until years after transmission occurred.

Modes of Transmission

Hepatitis C is spread by contact with blood and OPIM and occurs when these fluids enter the body of someone who is not infected. It is primarily sexually transmitted but sharing needles when "shooting" drugs can also spread it. Infection can pass from an infected mother to her child during birth. The risk of HCV infection in healthcare settings is low but infection can occur in healthcare workers who have repeated contact with blood and/or multiple needlestick injuries.

HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

Epidemiology

Currently, there are approximately one million reported cases of HIV infections in the United States with about 40,000 new HIV infections every year. Recent medical advances have reduced the number of deaths attributed to AIDS however there is still no cure nor a successful vaccine to prevent HIV infection. While infections were originally limited to male homosexuals, they now occur in heterosexuals as well. Recent statistics show increasing numbers of women who are infected with the virus.

Symptoms

The first symptoms of HIV may show up within a month of exposure and include a flu-like sickness with possible fever, diarrhea, fatigue, rash, lymphadenopathy, and joint pains. After this self-limiting illness, the HIV-infected person may be asymptomatic and in apparently good health for an indeterminate length of time. Then he or she may develop symptoms associated with generalized lymphadenopathy, fever for more than a month, significant weight loss, persistent diarrhea or a combination of any of these symptoms. AIDS is diagnosed by certain indicator diseases. These are pneumonia, esophageal cancers, neurological disorders or dementia and cancers such as Kaposi's sarcoma and non-Hodgkin's lymphoma.

Modes of Transmission

Human Immunodeficiency Virus (HIV) has been found in human blood, semen, vaginal secretion, saliva, tears, breast milk, urine, cerebrospinal fluid, and amniotic fluid. Transmission of the virus is implicated only in blood, semen, vaginal secretions, and possibly breast milk. While HIV has been found in very low concentration in some body fluids like saliva and tears, it is important to understand that finding a small amount in a body fluid does not necessarily mean that HIV can be transmitted by that body fluid. Contact with saliva, tears or sweat has never been shown to result in the transmission of the disease.

Modes of transmission include: sexual intercourse with an infected person, using contaminated needles, having parenteral, mucous membrane or non-intact skin contact with HIV infected blood or blood products, receiving transfusion of infected blood or transplants of infected organs, and transmission of the virus from mother to child around the time of birth. Occupational exposure can also occur in healthcare settings. Workers can be infected after being stuck with needles containing infected blood or, less frequently, after infected blood enters an open cut or mucous membrane. Scientists and medical authorities agree that HIV does not survive well in the environment making the possibility of environmental transmission remote.

UNIVERSAL PRECAUTIONS

Connecticut Orthopaedic Specialists observes and complies with the concept of "Universal Precautions". COS employees are required to treat all patients, all blood, and other potentially infectious materials as if infected with HIV, hepatitis B or C and/or any other diseases caused by bloodborne pathogens. Because it is not possible to identify patients with bloodborne diseases by standard medical procedures (such as medical history, laboratory tests, appearance or physical examination), blood and OPIM of all patients treated in our facilities office must be handled as if infectious. There are no exceptions to this policy. All employees must practice Universal Precautions.

WORK PRACTICE CONTROLS

It is important to perform tasks in a manner that minimizes the risk of exposure to blood or OPIM. When tasks are performed in the safest manner possible, exposure or risks are greatly reduced. COS employees are therefore trained on the use of appropriate work practice controls and are encouraged to ask their Health and Safety Site Representative or OSHA Compliance Officer if there are any questions or concerns. COS' work practices include the following:

- Hands must be washed immediately or as soon as feasible when gloves are removed
- Hands must be washed immediately or as soon as feasible following contact with blood or OPIM
- Contaminated needles and other contaminated sharps will not be bent, recapped or removed unless there is no feasible alternative or unless the action is required by a specific medical procedure
- If needles must be recapped or removed, the action will be accomplished by using a mechanical device or by a one-handed technique

- All contaminated sharps and other regulated waste will be disposed of into appropriate containers located as close as feasible to the area of use
- Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in areas where there is a reasonable likelihood of contamination
- Sharps containers will not be overfilled
- The practice of Universal Precautions is mandatory
- All tasks involving blood or OPIM must be performed in a manner that minimizes splashing, spraying, spattering and/or generation of droplets of these substances
- Mouth pipetting/suctioning of blood or OPIM is prohibited
- Food and drink will not be kept in refrigerators, shelves, cabinets or countertops where blood or OPIM are likely to be present
- Contaminated instruments, syringes and other sharp devices are not passed hand-to-hand.

SAFER SHARPS EVALUATION

Connecticut Orthopaedic Specialists OSHA Compliance Officer will solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation and selection of engineering and work practice controls. The solicitation and responses will then be documented and added to your OSHA Compliance Plan as needed or on an annual basis.

COS will conduct an initial review of the use of safer sharps in our practice. COS will give each participating employee the Evaluation of Safety Syringes and/or Other Safety Devices form (form # OS-018) to complete. Once all forms have been submitted the responses will then be summarized and results will be transposed to the Safer Sharps Review and Evaluation form (form # OS-017). The results will also be added to COS' Bloodborne Pathogens Exposure Control Plan. This Safer Sharps Evaluation will be conducted at least annually.

ENGINEERING CONTROLS

Engineering controls reduce the risk of exposure to blood or OPIM by eliminating, isolating or removing the hazard from the workplace. It is COS' policy to evaluate engineering controls on a regular basis and at least annually. If items and/or devices are found to be appropriate for your needs and, at the same time, reduce risks to your employees, their use should be implemented. Engineering controls include, but are not limited to:

- Hand washing facilities near or in all work areas (or antiseptic hand cleaner available)
- Eye wash station (within 100 feet or 10 seconds from exposure area) – *included in first aid kit*
- Needleless devices
- Self-sheathing needles, retractable needles or other needles or syringes with "built-in" engineering controls
- Scalpels and/or other blades which are retractable or have a shield that can be activated with the hand behind the blade

- Puncture-resistant sharps disposal containers
- Reusable sharps containers with sides that prevent items from falling out when containers are moved
- Resuscitation bags or other ventilation devices – *included in first aid kit*
- Plastic capillary tubes
- Plastic blood collections tubes
- Blunt suture needles

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment (PPE) is another way of minimizing exposure to blood and OPIM. It provides a barrier to protect the skin and mucous membranes from exposure. The selection of PPE depends upon the procedure and is performance-based. Routine procedures seldom require more than gloves. Invasive procedures, tasks where spattering and /or splashing are likely, may require gloves, masks, eye-protection and gowns. PPE that is provided in our facilities includes:

- Gloves, latex or latex-free exam gloves
- Gloves, sterile
- Masks
- Eye protection, safety glasses
- Eye protection, face shield
- Eye protection, other (protecting the sides of the eyes)
- Barrier garments, disposable
- Barrier garments (washable lab coats, scrubs, gowns, etc.)

Guidelines for Selecting PPE

- **Gloves** - Wear gloves anytime there is a risk of your hands having direct contact with blood or OPIM. Gloves must be worn when handling -items or touching surfaces that might be contaminated. Replace disposable gloves after each patient or as soon as possible if visibly soiled, torn or punctured. Never re -use disposable gloves.
- **Masks** - Wear a mask when there is a risk of splashing or spattering of blood or OPIM. The mask should fit snugly against the face. Change it when it gets wet and never let it "dangle" around the neck. Handle the mask by the strings and avoid touching the mask itself.
- **Eye Protection** - Safety glasses, a chin-length face shield or glasses equipped with non-perforated side shields are appropriate protection since the sides of the eyes are protected. Use eye - protection any time there is a risk of splashes, sprays or spattering of blood or OPIM.
- **Barrier Garments** - Selection of barrier garments is performance-based. Barrier garments can be either disposable or washable as long as they protect the skin, street clothes or uniform from exposure to blood and OPIM. Barrier garments must be removed and replaced as soon as possible when visibly soiled. Garments used as PPE must not be taken home to be laundered.

LAUNDRY

All soiled laundry or linen must be handled as if potentially contaminated with body fluids. All clean linen must be stored in an area where no soiled linen will come in contact with it. All soiled laundry or linen must be bagged at the site where it is used. It must be placed in bags that can be easily identified. PPE must be used by the person handling and laundering linens and soiled laundry. COS is contracted with a linen/laundry service for laundering our soiled linen and laundry. The name of the company is Pathacura.

HOUSEKEEPING

The term "housekeeping" is used to include all procedures involving cleaning and decontamination of environmental surfaces and equipment which may be contaminated with blood or OPIM. It is the overall responsibility of the Health and Safety Site Representative and the OSHA Compliance Officer to ensure that COS' facilities are maintained in a clean, sanitary and orderly manner. COS' employees are assigned certain responsibilities and must adhere to the following guidelines:

- Use a disinfectant that is EPA registered (SaniZide) or (A diluted bleach solution of 1 part bleach to 10 parts water is appropriate if it is mixed daily)
- All equipment and working surfaces must be cleaned after each procedure if there has been a reasonable likelihood of contamination while wearing PPE
- All equipment and working surfaces must be cleaned at the end of the day (or work shift) if they have been contaminated since the last cleansing
- Remove and replace all protective coverings, such as plastic, paper, etc. after each patient visit
- Inspect and decontaminate, on a regular basis, all reusable receptacles such as bins, cans, etc. that have a likelihood of becoming contaminated. Clean them immediately, or as soon as feasible when visibly contaminated while wearing PPE
- Ensure that sharps containers are easily accessible and located as close as feasible to the area where they are used
- Check disposable sharps containers regularly to ensure that they are not overfilled
- Check sharps containers to ensure that they are assembled correctly and are upright
- Discard non-sharp medical waste into appropriate containers immediately, or as soon as feasible
- Never manually open, empty or clean disposable sharps containers
- Equipment that may be contaminated with blood or OPIM must be cleaned and decontaminated prior to servicing and/or shipping
- Notify your Health and Safety Site Representative or OSHA Compliance Officer if there is a spill of blood or OPIM
- All work surfaces must be immediately cleaned after any spill of blood or OPIM while wearing PPE
- Obtain a spill kit or appropriate supplies (absorbent materials, utility gloves, cleaning material, including a detergent and a disinfection product and appropriate disposal containers)
- Employees are made aware of the location of these supplies

- Always use mechanical means (tongs, forceps, or brush and dust pan) to pick up any contaminated broken glass. NEVER pick up these items with your hands even if wearing gloves. Discard broken contaminated glass into a sharps container.

COS' internal housekeeping procedures are always be performed prior to the general cleaning done by our contracted housekeeping service, "Cleaning Services Group."

DISINFECTION AND STERILIZATION

Disinfection and sterilization procedures currently recommended by the Centers for Disease Control, the ADA, and the AMA are used for all reusable instruments, devices and other items that are contaminated with blood and/or OPIM. COS uses the following definitions as guidelines for appropriate sterilization and/or disinfection procedures:

- High level disinfection are used on all semi-critical care items that could be damaged by heat sterilization. Use a product labeled "disinfectant/sterilant" and leave the items immersed for the shorter time recommended by the manufacturer. (The longer time is used for "cold sterilization".)
- Intermediate level disinfection is not to be used on semi-critical care items. However is used for disinfection of non-critical care items that are contaminated with blood or OPIM. A bleach solution (1 part bleach to 10 parts water) is strong enough but must be mixed fresh daily. Wipe the item to be cleaned with the bleach solution (or a commercial disinfectant - SaniZide) and allow it to air dry.
- Low level disinfection is not necessary for non-critical care items that have not been contaminated with blood or OPIM. Proper cleaning is usually sufficient. If you choose to use a low-level disinfection, wipe or spray an EPA registered disinfectant on the surfaces of the cleaned items and let them air dry.
- Sterilization is the process that destroys all microorganisms (including viruses) and their spores. Sterilization can be accomplished by the use of steam (steam autoclave), dry heat, chemicals under pressure (chemical autoclave) or an EPA registered product that is labeled "disinfectant/sterilant" (sometimes referred to as "cold sterilization").
- Critical care items are all instruments and/or devices that are introduced directly into the bloodstream. They touch bone or penetrate tissue. All of these items are sterilized.
- Semi-critical care items are instruments that touch mucous membranes but do not touch bone or penetrate tissue. If the items are not damaged by heat, sterilize them or use a high-level disinfection process following the manufacturer's guidelines.
- Non-critical care items are equipment and environmental surfaces that will come into contact with intact skin only. Floors, exam tables, crutches, and countertops are examples of noncritical care items. Use intermediate-level disinfection for non-critical care items. (Cleaning alone is sufficient unless the items are visibly contaminated with blood.)
- Biological monitoring is a "spore test" and is the only way to ensure that heat sterilization is effectively killing all types of microorganisms. Check with the manufacturer of your sterilizer for

the proper spore test. You can mail the exposed test spores to an appropriate microbiology lab for testing or check them yourself in a special incubator designed for that purpose.

COMMUNICATION OF HAZARDS TO EMPLOYEES

Biohazard labels and signs are used to identify biohazardous materials such as biomedical waste, blood, specimens and other potentially infectious materials. These labels are used on all containers with biohazardous items. The labels are fluorescent orange or orange-red with lettering or symbols in a contrasting color. Red bags or red containers are allowed to be substituted for labels.

The Health and Safety Site Representative and OSHA Compliance Officer ensure that all of the following items, equipment, and/or containers are properly labeled as "biohazardous". COS employees should notify their Health and Safety Site Representative or OSHA Compliance Officer if they discover any items, equipment or containers that are not correctly labeled.

- All biohazardous waste containers, including bags and/or disposable sharps containers
- Biohazardous waste storage areas
- Contaminated laundry containers
- Reusable contaminated sharps containers
- Contaminated equipment
- Refrigerators and/or freezers containing blood, specimens or OPIM
- Containers used to store, transport, or ship blood or OPIM (Individual containers of blood or OPIM that are placed into a labeled container are exempt from this requirement. For example, a test tube rack can be labeled rather than each blood collection tube.)
- Signs will be posted at the entrance of designated "work areas" if it contains contaminated materials

EXPOSURE INCIDENTS: POST-EXPOSURE EVALUATIONS AND FOLLOW-UP

An exposure incident means a specific eye, mouth, other mucous membrane, non-intact skin or parenteral contact with blood or OPIM that result from the performance of an employee's duties. Always consider bloodborne exposure incidents to be matters of urgent medical concern. COS offers immediate medical evaluation and follow-up to all employees who have an exposure incident through our contracted medical providers Physician One Urgent Care and Stony Creek Urgent Care. The medical services rendered will be provided at no charge to the individual and is based on current recommendations from the Centers of Disease Control and Prevention (CDC).

Should an exposure incident occur, COS employees are instructed to immediately report the incident to their Health and Safety Site Representative and/or OSHA Compliance Officer. Details of the incident are important and must be recorded on the Bloodborne Exposure Incident Report form and, if applicable, the Sharps Injury Report and Sharps Injury Log.

Post-exposure evaluation includes:

- A blood sample must be drawn and tested as soon as feasible for HIV, hepatitis B and C if the exposed individual consents. If consent to test is not given, the sample must be kept for 90 days in case the individual elects to have the sample tested during that time frame.
- The individual will be advised that he or she is entitled to medical evaluation in addition to testing
- Counseling will be offered
- He or she will be advised to report any acute illness, which is accompanied by fever, within the next 12 weeks and to seek medical attention for any such occurrence
- If the initial test is seronegative for HIV, re-testing must be offered at 6 weeks, 12 weeks and 6 months after the incident based on recommendations of the consulting physician and current CDC guidelines.

STEPS TO TAKE IN CASE OF AN EXPOSURE INCIDENT

(If another designated healthcare provider is used)

If the COS employee involved in an exposure incident requests medical evaluation, they will be sent designated contracted healthcare provider (Physician One Urgent Care and Stony Creek Urgent Care) for testing, evaluation and other appropriate action immediately. COS will cover the medical expenses to provide post-exposure medical evaluation and follow-up based on current CDC recommendations. COS will provide the healthcare professional with the following per OSHA regulations:

1. A copy of the bloodborne pathogen standard
2. A description of the employees's duties as they relate to this exposure incident. (This information is on the Bloodborne Exposure Incident Report (form #OS-005) and the Sharps Injury Report (form # OS-014).
3. The route of entry and circumstances surrounding the incident (This information is also on the Exposure/Sharps Incident Report or Employee Incident Report)
4. Information COS may have in the COS employee's medical record as it relates to HBV vaccination, other exposure incidents, etc. (This disclosure is allowed by HIPAA Privacy as it applies to Public Health and is required by law.)
5. Results of the patient's blood testing, if known.

If a source patient is involved in the reported incident, a member of COS' health and safety committee, OSHA compliance officer or administrative personnel will explain the situation to him or her and, if possible, obtain consent to test his or her blood. Complete a copy of the Consent to Draw and Test Blood form (form # OS-006).

COS will have the employee complete a Bloodborne Exposure Incident Report and a Sharps Injury Report. The healthcare provider to whom the employee will see will be furnished with this information. OSHA requires COS that the employee complete all of the information on the Bloodborne Exposure Incident Report. The completed information will be used by management to evaluate how the exposure occurred and what can be done to prevent a recurrence of the type of occupational injury.

If the employee declines medical evaluation and follow-up, the employee will need to sign a copy of the Informed Refusal of Medical Evaluation form (form # OS-012). Once the form is signed it will be placed with the employee's confidential medical records and no further action is required. COS encourages employees that have been exposed under-go the testing perimeters and they will be explain the risks to assist the employee in making the right decision.

The healthcare provider must send a written opinion to you stating that the employee was notified of the results and the need, if any, for follow-up. This opinion will inform COS if the hepatitis B vaccine was required and if it was given. Other information resulting from the evaluation is confidential and is released only to the employee.

The exposed employee will be given a copy of this written opinion within 15 days and COS will keep another copy with the employee's confidential medical records that the Human Resources Department maintains.

If it is a Sharps Injury, the injury will be recorded on the Sharps Injury Log (form # OS-015). Please note this is not confidential information since no names are recorded on the log. It will help identify patterns to sharps injuries so problems can be corrected. For example, change to a different device or provide additional training if COS identifies injuries caused by the same syringe or medical device.

RECORDKEEPING

OSHA has specific recordkeeping requirements. Since records are used to document compliance with the bloodborne pathogen standard, it is important that COS keeps and maintains accurate records. The following records that COS is required to maintain are as follows:

Training Records

An important part of COS Exposure Control Plan is employee training. It is required at the time of hire and prior to assignment to any "at risk" tasks. OSHA also requires annual "re-training". OSHA requires that COS keeps all training records for 3 years. The training records consist of the following:

1. The dates of the training sessions.
2. The contents or a summary of the training sessions.
3. The names and qualifications of the persons conducting the training.
4. The names and job titles of all persons attending the training sessions.

All training records are made available to employees for examination and copying and to OSHA.

Medical Records (form # OS-009)

Employee exposure and medical records will be established for each employee and will include the following:

1. Name, address and Social Security number
2. Copies and information on his/her hepatitis B vaccination records
3. Any records which may pertain to his/her inability to receive the HBV vaccination
4. Documentation of all exposure incidents including date, location, name of source patient, type of incident (needlestick, etc.)
5. Copies of all physical examinations, testing and follow-up results as they relate to his/her ability to receive vaccination or to any post-exposure evaluation
6. Information provided to another healthcare professional regarding the employee's exposure and possible need for hepatitis B vaccination
7. Healthcare professional's written opinion as to whether hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination (form #OS-025)

These records will be kept confidential and in a secure location. They will not to be disclosed to anyone within COS or to anyone outside of the confines of COS except as required by law. The records are available to the employee about whom the records pertain, or the employee's designated representative, and to OSHA. Medical records will be kept for 30 years plus the term of employment.

Informed Refusal for Hepatitis B Vaccination (form # OS-Oh)

If an employee refuses vaccination for hepatitis B for any reason, he or she must sign the Informed Refusal, or Declination (form # OS-Oil) form. The wording OSHA requires is very specific. This form, when signed, becomes part of an employee's medical record and, as such, must be kept confidential. 'As part of an employee's medical record it must be kept for 30 years plus the term of employment. If records of an employee's vaccination history are not available, he or she should sign the Declination form and check the appropriate statement at the bottom of the form. This acknowledges that the individual has been previously vaccinated but does not have written proof.

Informed Refusal of Post-Exposure Evaluation (form # OS-012)

If an employee has a bloodborne exposure incident and refuses post-exposure evaluation and follow-up for any reason, he or she must sign the Informed Refusal of Post-Exposure Medical Evaluation form. This form becomes part of the employee's confidential medical record and will be kept for 30 years plus the term of employment.

Bloodborne Pathogen Exposure Incident Report (form # OS-005)

All bloodborne pathogen exposure incidents will be reported and documented. The report becomes part of the employee's confidential medical record and will be kept for 30 years plus the term of employment.

Sharps Injury Report (form # OS-014)

This form will be used to report all sharps-related bloodborne pathogen exposure incidents. As with the Bloodborne Pathogen Exposure Incident Report above, this report becomes part of the employee's confidential medical record and will be kept for 30 years plus the term of employment.

Sharps Injury Log (form # OS-015)

OSHA's recordkeeping regulations require COS to keep a log of sharps injuries. The purpose of the log is to identify certain patterns, or re-occurrences, of sharps injuries. The name of the exposed individual is not included on the form so a Sharps Injury Log does not fall under confidentiality requirements. The Sharps Injury Log must contain:

1. The type and brand of device involved in the incident.
2. The department or work area where the exposure incident occurred.
3. An explanation of how the injury occurred.

EMERGENCY PROCEDURES/CONTINGENCY PLANS

Blood Spills

If there is a spill of blood or OPIM, immediately notify your Health and Safety Site Representative and/or OSHA Compliance Officer. Use a spill kit and/or appropriate materials to contain, clean and disinfect spills. It is mandatory that appropriate PPE be worn for clean-up procedures. If employees are not sure of the appropriate action, they should consult their Health and Safety Site Representative and/or OSHA Compliance Officer prior to cleaning the spill.

Life-Threatening Emergencies

Sometimes an emergency situation occurs and there may not be time to don appropriate PPE. If possible, use practices consistent with Universal Precautions. When the situation is stabilized, immediately use necessary equipment. In such an emergency, the decision not to use PPE rests solely with the employee. He or she should be informed that they are expected to exercise professional judgment in this action and should be aware that he or she will be asked to explain the reasoning.

WORK AREAS AND NON-WORK AREAS

The purpose for designating Work Areas and Non-Work Areas is to avoid cross contamination. All work and non-work areas are adequately lighted and all floor surfaces are dry and/or skid resistant.

Use the following guidelines and remove contaminated PPE before entering any area classified as a Non-Work Area:

Work Areas Guidelines

Appropriate PPE must be worn in these areas if exposure to blood or OPIM can be reasonably anticipated. The **guidelines** for Work Areas are as follows:

It is reasonable to expect exposure to blood and/or other potentially infectious materials in certain areas. Therefore, eating, drinking, smoking, applying cosmetics or lip balm, handling contact lenses are prohibited in areas where contamination is likely. Food and drink are never permitted in work areas and must not be left on countertops in any area where there is a reasonable likelihood of contamination. Work areas usually include all patient treatment areas, labs, sterilization areas and hallways connecting these areas. Work areas will be maintained in a clean and orderly manner.

Non-Work Areas Guidelines

There are no procedures performed in these areas that could result in contamination with blood or OPIM. PPE must be removed prior to entering these areas. The **guidelines** for Non-Work Areas are as follows:

These areas usually include staff lounges, kitchens, administrative and/or clerical areas, front office, reception or waiting room, and other business-related offices or areas.

TRAINING REQUIREMENTS (See forms #OS-010 and #OS-013)

Training will be provided at the time of initial assignment to tasks where occupational exposure to blood and OPIM may occur. Training will also be conducted at least annually thereafter. Training will be provided during work hours and at no cost to our employees. In the event employees are given new tasks, or existing tasks are modified, additional and appropriate training will be conducted. The training will be documented and the records will be kept for 3 years.

Training will include the following elements:

- An accessible copy of the Bloodborne Pathogen Standard
- An explanation of the epidemiology and symptoms of bloodborne diseases
- Modes of transmission of bloodborne pathogens
- An explanation of your bloodborne exposure control plan, where it is located, and how a copy can be obtained
- How to recognize tasks which may result in exposure to blood and OPIM
- An explanation of COS' engineering controls, work practice controls and PPE
- The type of PPE available and where it is located
- How to select appropriate PPE and your minimum requirements for various tasks and procedures
- How to properly dispose of PPE which is soiled and/or contaminated

- Information on the hepatitis B vaccination including benefits, efficacy, etc. and that it is offered free of charge
- Who to contact in case of an emergency involving exposure to blood or OPIM
- What to do in case of an exposure incident
- Information on post exposure evaluation and follow-up treatment, which is available at no charge to COS employees
- An explanation of the color code and biohazard symbol
- How to handle biomedical waste generated in a COS office



REGULATED WASTE MANAGEMENT

This standard refers to Regulated Waste, Medical Waste, Biomedical Waste and Biohazardous Waste. These terms are meant to be interchangeable for the purposes of this Standard.

BIOMEDICAL WASTE PLAN

Policy

Connecticut Orthopaedic Specialists (COS) has created and implemented a Biomedical Waste Plan that addresses the handling, storage and disposal of Biohazardous Waste.

Procedure

COS trains our employees on the handling, storage and disposal of Biohazardous Waste.

Our **Biomedical Waste Plan** consists of the following elements:

Handling Medical Waste

Policy

All of our employees are required to follow our basic rules for handling medical waste.

Procedure

COS trains all of our employees to adhere to the **following basic rules** when handling medical waste:

- We identify and segregate Biomedical (or Biohazardous) Waste from other waste at its **point of origin** (or as close as feasible to the area where it is generated).
- All non-sharp Biohazardous Waste is disposed of directly into red bags identified with biohazard symbols.
- All items classified as sharps are placed immediately into puncture-resistant, leak-proof sharps containers.
- Sharps containers are set up in such a way that the biohazard symbols are clearly visible and the lids are securely fastened in place. They are never to exceed the fill line (approximately 1" from the top). It is clearly understood that under no circumstances are disposable sharps containers to be emptied and reused.
- All employees who handle Biohazardous Waste wear appropriate PPE. All PPE that comes in contact with Biohazardous materials is disposed of into red Biohazardous Waste bags.



Connecticut Orthopaedic Specialists

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- When filled, all sharps containers and red bags are sealed promptly and properly in the area of use. Containers and/or bags of biomedical waste are securely closed prior to moving.
- All biomedical waste prepared for off-site transport is enclosed in a rigid type container and is then labeled for transport.
- Our employees report any concerns about biomedical waste to our Health and Safety Site Representative who then informs the OSHA Compliance Officer.
- All of our employees observe the Biohazard Symbol at all times

Labeling Biomedical Waste for Transport

Policy

Biomedical Waste is labeled prior to transport off-site.

Procedure

We ensure the labeling of all Biomedical Waste to be transported off-site. The label is securely attached to the outer layer of packaging and it is clearly legible. The following information is included on the label:

- Our name and address
- The date the first biomedical waste was placed into the container and the date the container was closed and sealed
- The International Biohazardous Symbol
- The phrase “Biohazardous Waste”, “Infectious Waste”, “Biomedical Waste”, or equivalent wording

Storage of Biohazardous Waste

Policy

All on-site storage of Biohazardous Waste is carefully handled.

Procedure

All on—site storage of Biohazardous Waste is in an area away from general traffic flow patterns and accessible only to authorized personnel. Storage of Biohazardous Waste is not greater than 2 days. This time period commences when the first item of non-sharp, biohazardous waste is placed in the container or bag. Sharps containers that contain only sharps can be kept until full.

All areas primarily used for the storage of Biohazardous Waste are constructed of smooth, easily cleanable materials that are leak-proof and capable of being maintained in a sanitary condition. All storage areas are kept clean and orderly. Outdoor areas and containers are secured from vandalism. All outdoor storage areas are conspicuously marked with the International Biohazard Symbol.

All Biohazardous Waste is treated either by heat, incineration or other equivalent methods suitable for hazard inactivation. Our contracted off-site waste hauler, when used, is registered

with the Department of Environmental Regulations.

Co-Mixing Waste

Policy

It is never permissible to dispose of any material identified as biohazardous into regular trash receptacles.

Procedure

We always comply with the following rules for co—mixing waste:

- All Biohazardous Waste, which is mixed with Hazardous Waste, is managed as Hazardous Waste.
- All Biohazardous Waste, which is mixed with Radioactive Waste, is managed as Radioactive Waste.
- All solid waste, other than Hazardous or Radioactive Waste, which is mixed with Biohazardous Waste, is managed as Biohazardous Waste.

Handling Spills

Policy

Surfaces contaminated with spilled and/or leaked Biohazardous Waste are promptly cleaned under the supervision of our Health and Safety Site Representative.

Procedure

Appropriate PPE is worn by all employees handling spills of Biohazardous Waste or what is suspected to be Biohazardous Waste. Surfaces contaminated with spilled and/or leaked Biohazardous Waste are cleaned of all liquids using absorbent materials (paper towels, kitty litter or a commercial product for spills). After the liquids have been absorbed, the surface is cleaned with a solution of industrial strength detergent to remove any remaining liquids and/or soil. After cleaning, the surface and/or area is thoroughly disinfected. All materials used to clean the spill are disposed of into red Biohazardous Waste bags. When the task is complete, all PPE worn while cleaning and disinfecting the spill area is disposed of into red Biohazardous Waste bags. To disinfect the surface and/or area, we use one of the following products:

- A bleach solution containing 1 part bleach to 10 parts water mixed fresh daily
- A chemical germicide that is registered by the EPA as hospital grade disinfectant.

If broken glass, hard plastic, syringes, blades, needles and other contaminated items capable of lacerating the skin are present, we do NOT pick up the items with our hands. We use a whiskbroom and dustpan, forceps or other devices. We place all contaminated sharps into an appropriate sharps container which is brought to the area.



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The

Orthopaedic Group

OrthopedicHealth



Center For Orthopaedics

SHORELINE

ORTHOPEDICS & SPORTS MEDICINE

Training

Policy

All of our employees receive training on Biohazardous Waste as it applies to their tasks.

Procedure

All of our medical employees receive this training on Biohazardous Waste within 10 days of hire and to any employee prior to assignment to any task that requires the handling of biomedical waste and OPIM.

Our training includes:

- The definition of Biohazardous Waste that is generated by our practice
- Point-of-origin disposal and segregation of Biohazardous Waste
- How to properly assemble and use sharps containers
- How to properly move biomedical waste from disposal area to storage area
- The use and disposal of PPE while handling any biomedical waste
- On-site biomedical waste storage requirements including where and how the waste is stored
- Our plan for cleaning spills and the location of appropriate PPE and cleaning supplies
- Training is conducted at least annually and is required of all employees who handle biomedical waste

EXHIBIT H



American College of Radiology

Magnetic Resonance Imaging Services of

Connecticut Orthopaedic Specialists, PC

2416 Whitney Ave
Hamden, Connecticut 06518

were surveyed by the
Committee on MRI Accreditation of the
Commission on Quality and Safety

The following magnet was approved

General Electric SIGNA 1.5T 2001

For

Spine, MSK

Accredited from:

May 01, 2014 through September 27, 2017

CHAIRMAN, COMMITTEE ON MRI ACCREDITATION

PRESIDENT, AMERICAN COLLEGE OF RADIOLOGY



American College of Radiology

Magnetic Resonance Imaging Services of

Connecticut Orthopaedic Specialists, PC

84 North Main Street
Branford, Connecticut 06405

were surveyed by the
Committee on MRI Accreditation of the
Commission on Quality and Safety

The following magnet was approved

General Electric 1.5 GE SIGNA LX 2006

For

Spine, MSK

Accredited from:

May 08, 2014 through February 02, 2018

Anthony J. Scuderi, M.D.

CHAIRMAN, COMMITTEE ON MRI ACCREDITATION

Paul H. Ellenbogen, M.D.

PRESIDENT, AMERICAN COLLEGE OF RADIOLOGY

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EXHIBIT I

000175



Charity Care Policy

COS Imaging Services

PURPOSE:

To provide a policy and procedure for the determination and handling of Connecticut Orthopaedic Specialists, P.C. (COS) Charity Care for patients who require imaging services. This policy and procedure is offered by COS as a means by which patients who require imaging services but can otherwise not afford this service. Any COS patient that either has no health insurance or whose household income is less than 250% of the Federal Income Poverty Guideline will be considered for reduced rate consideration.

PROCEDURE:

Patients may be required to complete a financial assistance application and / or provide the following requested documents. COS may also at its own discretion chose to offer the discounted rate without verification of documentation.

- Copies of items to support income
 - Pay stubs, bank statements, tax returns or other proof of income
- Copies of monthly expenses
 - Mortgage statement, rent check, utilities
- Number of dependants in household

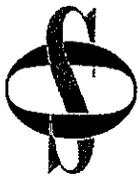
COS will endeavor to work out a payment plan that will allow all patients regardless of their financial situation to be able to afford necessary imaging services. If necessary, and at it's discretion, COS may elect to provide the service at no cost to the patient.

EXHIBIT J

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Exhibit J (1)

2015 Total COS MRI Scans by Patient Towns



Connecticut Orthopaedic Specialists

THE EXPERIENCE MATTERS

2015 MRI Scans by Town*

Zip Code	City	# of Scans
06401	Ansonia, CT	58
06001	Avon, CT	2
06403	Beacon Falls, C	15
06037	Berlin, CT	9
06524	Bethany, CT	76
06801	Bethel, CT	2
06751	Bethlehem, CT	1
06405	Branford, CT	625
06604	Bridgeport, CT	32
06010	Bristol, CT	9
06013	Burlington, CT	2
06409	Centerbrook, C	2
06410	Cheshire, CT	295
06412	Chester, CT	8
06413	Clinton, CT	121
06414	Cobalt, CT	1
06415	Colchester, CT	2
06238	Coventry, CT	1
06416	Cromwell, CT	5
06810	Danbury, CT	6
06417	Deep River, CT	12
06418	Derby, CT	35
06422	Durham, CT	39
06023	East Berlin, CT	2
06423	East Haddam,	2
06424	East Hampton,	1

Zip Code	City	# of Scans
06762	Middlebury, CT	2
06455	Middlefield, CT	8
06457	Middletown, C	36
06460	Milford, CT	503
06467	Milldale, CT	1
06468	Monroe, CT	22
06469	Moodus, CT	3
06354	Moosup, CT	1
06355	Mystic, CT	3
06770	Naugatuck, CT	23
06053	New Britain, C	6
06840	New Canaan, C	1
06812	New Fairfield, I	1
06503	New Haven, C	626
06320	New London, C	2
06776	New Milford, C	1
06111	Newington, CT	7
06470	Newtown, CT	2
06357	Niantic, CT	11
06471	North Branfor	152
06473	North Haven, C	416
06778	Northfield, CT	1
06472	Northford, CT	130
06850	Norwalk, CT	6
06360	Norwich, CT	1
06370	Oakdale, CT	1

Zip Code	City	# of Scans
06288	Storrs, CT	1
06614	Straford, CT	56
06786	Terryville, CT	4
06084	Tolland, CT	1
06790	Torrington, CT	2
06611	Trumbull, CT	44
06382	Uncasville, CT	1
06066	Vernon, CT	1
06492	Wallingford, C	436
06704	Waterbury, CT	24
06385	Waterford, CT	8
06795	Watertown, CT	3
06107	West Hartford,	6
06516	West Haven, C	517
06093	West Suffield,	2
06498	Westbrook, CT	33
06883	Weston, CT	2
06880	Westport, CT	5
06109	Wethersfield, C	4
06279	Willington, CT	1
06095	Windsor, CT	1
06096	Windsor Locks	1
06716	Wolcott, CT	18
06525	Woodbridge, C	158
06798	Woodbury, CT	1
06492	Yalesville, CT	6

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06118	East Hartford,	2	06870	Old Greenwich	1
06512	East Haven, C	450	06371	Old Lyme, CT	28
06333	East Lyme, CT	5	06475	Old Saybrook,	39
06612	Easton, CT	3	06477	Orange, CT	232
06029	Ellington, CT	1	06478	Oxford, CT	44
06426	Essex, CT	12	06379	Pawcatuck, CT	1
06824	Fairfield, CT	15	06062	Plainville, CT	7
06033	Glastonbury, C	5	06479	Plantsville, CT	11
06351	Griswold, CT	1	06480	Portland, CT	4
06340	Groton, CT	2	06712	Prospect, CT	27
06437	Guilford, CT	398	06375	Quaker Hill, CT	3
06438	Haddam, CT	3	06896	Redding, CT	2
06511	Hamden, CT	798	06877	Ridgefield, CT	1
06247	Hampton, CT	1	06420	Salem, CT	3
06105	Hartford, CT	2	06482	Sandy Hook, C	3
06791	Harwinton, CT	1	06483	Seymour, CT	69
06441	Higganum, CT	6	06484	Shelton, CT	56
06442	Ivoryton, CT	8	06073	South Glastont	1
06419	Killingworth, C	57	06074	South Windsor,	2
06339	Ledyard, CT	1	06488	Southbury, CT	10
06443	Madison, CT	299	06489	Southington, C	35
06040	Manchester, CT	4	06890	Southport, CT	2
06444	Marion, CT	2	06076	Stafford Spring	1
06447	Marlborough, (2	06902	Stamford, CT	2
06450	Meriden, CT	148	06378	Stonington, CT	2

*Does not include scans of non-Connecticut residents

000180

Orange MRI Town	Scan
North Have	416
East Haven	450
New Haven	626
Derby	35
Milford	503
Orange	232
Shelton	56
Stratford	56
Woodbridgr	158
W. Haven	517
	3049

Essex MRI Town	Scan
Essex	12
Madison	299
Guilford	398
Clinton	121
Old Saybro	39
Westbrook	33
Old Lyme	28
Deep River	12
Chester	8
	950

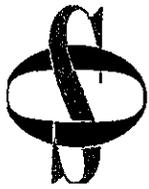
000181

Exhibit J (2)

COS Branford

2015 COS Branford MRI Scans by Patient Towns

000182



Connecticut Orthopaedic Specialists

THE EXPERIENCE MATTERS

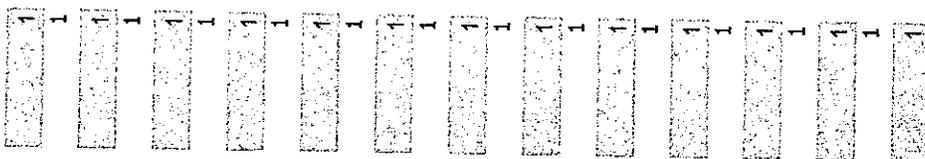
2015 Branford MRI Zip Code Analysis by Volume

Zip code	City	State	Units
06405	Branford	CT	565
06437	Gulford	CT	369
06512	East Haven	CT	335
06516	West Haven	CT	279
06443	Madison	CT	276
06460	Millford	CT	263
06471	North Branford	CT	134
06473	North Haven	CT	125
06413	Clinton	CT	114
06492	Wallingford	CT	108
06513	New Haven	CT	100
06472	Northford	CT	87
06477	Orange	CT	82
06410	Cheshire	CT	56
06512	New Haven	CT	56
06513	East Haven	CT	55
06514	Hamden	CT	55
06511	New Haven	CT	51
06419	Killingworth	CT	50
06525	Woodbridge	CT	46
06518	Hamden	CT	45
06475	Old Saybrook	CT	36
06515	New Haven	CT	31
06517	Hamden	CT	29
06498	Westbrook	CT	28
06422	Durham	CT	25
06450	Meriden	CT	25

Zip Code	City	State	Units
06053	New Britain	CT	4
06111	Newington	CT	4
06037	Berlin	CT	3
29909	Bluffton	SC	3
06606	Bridgeport	CT	3
06825	Fairfield	CT	3
06040	Manchester	CT	3
06469	Moodus	CT	3
06355	Mystic	CT	3
06712	Prospect	CT	3
06375	Quaker Hill	CT	3
06420	Salem	CT	3
06880	Westport	CT	3
06403	Beacon Falls	CT	2
06801	Bethel	CT	2
02813	Charlestown	RI	2
06415	Colchester	CT	2
06811	Danbury	CT	2
06423	East Haddam	CT	2
06612	Easton	CT	2
06438	Haddam	CT	2
06455	Middlefield	CT	2
06320	New London	CT	2
06850	Norwalk	CT	2
06855	Norwalk	CT	2
06074	South Windsor	CT	2
06488	Southbury	CT	2

Zip Code	City	State
28277	Charlotte	NC
28211	Charlotte	NC
01507	Charlton	MA
7928	Chatham	NJ
05038	Chelsea	VT
46304	Chesterton	IN
06414	Cobalt	CT
33071	Coral Springs	FL
92118	Coronado	CA
6416	Cromwell	CT
75204	Dallas	TX
30032	Decatur	GA
01062	Florence	MA
53732	Franklin	WI
11530	Garden City	NY
6033	Glastonbury	CT
53220	Greenfield	WI
6351	Griswold	CT
06340	Groton	CT
6511	Hamden	CT
06247	Hampton	CT
27944	Hertford	NC
12533	Hopewell Junction	NY
77063	Houston	TX
04449	Hudson	ME
32225	Jacksonville	FL
02835	Jamestown	RI

000183



000184

06371	Old Lyme	CT	25
06401	Ansonia	CT	19
06519	New Haven	CT	19
06484	Shelton	CT	17
06611	Trumbull	CT	16
06614	Stratford	CT	14
06483	Seymour	CT	15
06417	Deep River	CT	12
06457	Middletown	CT	12
06510	New Haven	CT	11
06426	Essex	CT	10
06357	Niantic	CT	10
06524	Bethany	CT	8
06385	Waterford	CT	8
06412	Chester	CT	7
06442	Ivoryton	CT	7
06468	Monroe	CT	7
06418	Derby	CT	6
06441	Higganum	CT	6
06478	Oxford	CT	6
06489	Southington	CT	6
06770	Naugatuck	CT	5
06010	Bristol	CT	4
06333	East Lyme	CT	4
06824	Fairfield	CT	4

06890	Southport	CT	2
06902	Stamford	CT	2
06378	Stonington	CT	2
34997	Stuart	FL	2
78332	Alice	TX	1
27502	Apex	NC	1
02474	Arlington	MA	1
06001	Avon	CT	1
06751	Bethlehem	CT	1
04614	Blue Hill	ME	1
33486	Boca Raton	FL	1
02116	Boston	MA	1
06604	Bridgeport	CT	1
06605	Bridgeport	CT	1
06608	Bridgeport	CT	1
02135	Brighton	MA	1
62634	Broadwell	IL	1
11205	Brooklyn	NY	1
11222	Brooklyn	NY	1
34604	Brookville	FL	1
06013	Burlington	CT	1
20866	Burtonsville	MD	1
28428	Carolina Beach	NC	1
06409	Centerbrook	CT	1
20151	Chantilly	VA	1

30022	Johns Creek	GA	
33477	Jupiter	FL	
90046	Los Angeles	CA	
06354	MOOSUP	CT	
3254	Moultonboro	NH	
10552	Mount Vernon	NY	
29576	Murrells Inlet	SC	
34112	Naples	FL	
2746	New Bedford	MA	
53151	New Berlin	WI	
13413	New Hartford	NY	
06532	New Haven	CT	
10014	New York	NY	
10021	New York	NY	
10028	New York	NY	
10028	New York	NY	
6470	Newtown	CT	
02852	North Kingstov	RI	
34287	North Port	FL	
06360	Norwich	CT	
6370	Oakdale	CT	
06870	Old Greenwich	CT	
32174	Ormond Beach	FL	
06379	Pawcatuck	CT	
96782	Pearl City	HI	

Zip Code City State Units
08861 Perth Amboy NJ 1

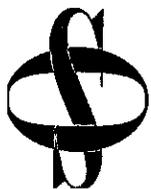
06062	Plainville	CT	1
08742	Point Pleasant	NJ	1
34952	Port St Lucie	FL	1
85142	Queen Creek	AZ	1
06482	Sandy Hook	CT	1
33777	Seminole	FL	1
25181	Seth	WV	1
11787	Smithtown	NY	1
12580	Staatsburg	NY	1
10980	Stony Point	NY	1
12582	Stormville	NY	1
85374	Surprise	AZ	1
33603	Tampa	FL	1
06786	Terryville	CT	1
32163	The Villages	FL	1
06382	Uncasville	CT	1
34285	Venice	FL	1
06066	Vernon	CT	1
22180	Vienna	VA	1
02081	Walpole	MA	2
06705	Waterbury	CT	1
06706	Waterbury	CT	1
06708	Waterbury	CT	1
33414	Wellington	FL	1
06095	Windsor	CT	1
06492	Yalesville	CT	1

Exhibit J (3)

COS Hamden

2015 COS Hamden MRI Scans by Patient Towns

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Connecticut Orthopaedic Specialists

THE EXPERIENCE MATTERS

2015 Hamden MRI Zip Code Analysis by Volume

Zip Code	City	State	Units
06492	Wallingford	CT	328
06473	North Haven	CT	291
06514	Hamden	CT	271
06518	Hamden	CT	246
06460	Milford	CT	240
06410	Cheshire	CT	239
06516	West Haven	CT	238
06517	Hamden	CT	151
06477	Orange	CT	150
06450	Meriden	CT	123
06511	New Haven	CT	119
06515	New Haven	CT	112
06525	Woodbridge	CT	112
06513	New Haven	CT	79
06524	Bethany	CT	68
06405	Branford	CT	60
06483	Seymour	CT	54
06512	East Haven	CT	47
06472	Northford	CT	43
06614	Stratford	CT	42
06401	Ansonia	CT	39
06484	Shelton	CT	39
06478	Oxford	CT	38
06418	Derby	CT	29
06437	Gulford	CT	29
06489	Southington	CT	29
06611	Trumbull	CT	28
06498	Westbrook	CT	5
06492	Yalesville	CT	5
06605	Bridgeport	CT	4
06416	Cromwell	CT	4
06810	Danbury	CT	4
06824	Fairfield	CT	4
06825	Fairfield	CT	4
06033	Glastonbury	CT	4
06480	Portland	CT	4
06109	Wethersfield	CT	4
06608	Bridgeport	CT	3
06111	Newington	CT	3
06371	Old Lyme	CT	3
06475	Old Saybrook	CT	3
01262	Stockbridge	MA	3
06704	Waterbury	CT	3
06795	Watertown	CT	3
06107	West Hartford	CT	3
75002	Allen	TX	2
06604	Bridgeport	CT	2
06607	Bridgeport	CT	2
06023	East Berlin	CT	2
06118-2370	East Hartford	CT	2
06426	Essex	CT	2
06340	Groton	CT	2
07039	Livingston	NJ	2
06444	Marion	CT	2
11249-3259	Brooklyn	NY	1
80020-9515	Broomfield	CO	1
30518	Buford	GA	1
1803	Burlington	MA	1
06013	Burlington	CT	1
81623	Carbondale	CO	1
12033	Castleton	NY	1
6409	Centerbrook	CT	1
06412	Chester	CT	1
6238	Coventry	CT	1
46307	Crown Point	IN	1
52807	Davenport	IA	1
21035	Davidsonville	MD	1
2026	Dedham	MA	1
03038	Derry	NH	1
48239	Detroit	MI	1
84020	Draper	UT	1
6424	East Hampton	CT	1
01028	East Longmead	MA	1
6333	East Lyme	CT	1
06612	Easton	CT	1
92020	El Cajon	CA	1
06029	Ellington	CT	1
11735	Farmingdale	NY	1
33312	Fort Lauderdale	FL	1
33907	Fort Myers	FL	1
11530	Garden City	NY	1

000189

06519	New Haven	CT	26
06457	Middletown	CT	24
06712	Prospect	CT	24
06443	Madison	CT	23
06770	Naugatuck	CT	18
06471	North Branford	CT	18
06716	Wolcott	CT	18
06468	Monroe	CT	15
06422	Durham	CT	14
06403	Beacon Falls	CT	13
06512	New Haven	CT	12
06513	East Haven	CT	13
06479	Plainville	CT	11
06606	Bridgeport	CT	10
06488	Southbury	CT	8
06708	Waterbury	CT	8
06413	Clinton	CT	7
06419	Killingworth	CT	7
06706	Waterbury	CT	7
06037	Berlin	CT	6
06455	Middlefield	CT	6
06510	New Haven	CT	6
06062	Plainville	CT	6
06610	Bridgeport	CT	5
06010	Bristol	CT	5

Zip Code	City	State	Units
06812	New Fairfield	CT	1

06447	Marlborough	CT	2
06762	Middlebury	CT	2
06053	New Britain	CT	2
01950-3050	Newburyport	MA	2
06357	Niantic	CT	2
07446	Ramsey	NJ	2
06896	Redding	CT	2
06482	Sandy Hook	CT	2
06786	Terryville	CT	2
06790	Torrington	CT	2
06710	Waterbury	CT	2
06110	West Hartford	CT	2
06093	West Suffield	CT	2
06883	Weston	CT	2
06880	Westport	CT	2
12208-3331	Albany	NY	1
11701	Amityville	NY	1
06001	Avon	CT	1
11933-1616	Baiting Hollow	NY	1
07920	Basking Ridge	NJ	1
08502	Belle Mead	NJ	1
07922	Berley Heights	NJ	1
48301	Bloomfield Hill	MI	1
28777	Bremen	NC	1
10708	Bronxville	NY	1

Zip Code	City	State	Units
06096	Windsor Locks	CT	1

10923	Garnerville	NY	1
91205-2036	Glendale	CA	1
27858-1607	Greenville	NC	1
12834	Greenwich	NY	1
966	Guaynabo	PR	1
06438	Haddam	CT	1
6105	Hartford	CT	1
06112	Hartford	CT	1
6791	Hartwinton	CT	1
06442	Ivoryton	CT	1
2130	Jamaica Plains	MA	1
33458	Jupiter	FL	1
11754	Kings Park	NY	1
12401	Kingston	NY	1
03766-4417	Lebanon	NH	1
06339	Ledyard	CT	1
6040	Manchester	CT	1
01756	Mendon	MA	1
6467	Milldale	CT	1
44654	Millersburg	OH	1
12549	Montgomery	NY	1
08057	Moorestown	NJ	1
60540	Naperville	IL	1
11767	Nesconset	NY	1
6840	NEW CANAAN	CT	1

06798	Woodbury	CT	1
07481	Wyckoff	NJ	1

06503	New Haven	CT	1
06505	New Haven	CT	1
06525	New Haven	CT	1
06776	New Milford	CT	1
77358	New Waverly	TX	1
10018	New York	NY	1
19702-8506	Newark	DE	1
06470	Newtown	CT	1
07006	North Caldwell	NJ	1
34287-2156	North Port	FL	1
06778	Northfield	CT	1
06850	Norwalk	CT	1
06851	Norwalk	CT	1
07436	Oakland	NJ	1
66062	Olathe	KS	1
07050	Orange	NJ	1
32174	Ormond Beach	FL	1
07652	Paramus	NJ	1
85016-4604	Phoenix	AZ	1
11803	Plainview	NY	1
33981	Port Charlotte	FL	1
34952-6620	Port St Lucie	FL	1
03801	Portsmouth	NH	1
12603	Poughkeepsie	NY	1
27606	Raleigh	NC	1
06877	Ridgefield	CT	1
07456	Ringwood	NJ	1
33579-2316	Riverview	FL	1
08880	S Bound Brook	NJ	1
55116	Saint Paul	MN	1
12159	Slingerlands	NY	1
11787	Smithtown	NY	1
06073	South Glastonct	CT	1
06076	Stafford Springs	CT	1
10312	Staten Island	NY	1
10980	Stony Point	NY	1

06268	Storrs	CT	1
53589	Stoughton	WI	1
11791	Syosset	NY	1
07666	Teaneck	NJ	1
10594	Thornwood	NY	1
06084	Tolland	CT	1
34293	Verice	FL	1
02889	Warwick	RI	1
06705	Waterbury	CT	1
02481	Wellesley	MA	1
11704	West Babylon	NY	1
06107-2053	West Hartford	CT	1
07675	Westwood	NJ	1
06279	Willington	CT	1

000192

			New Haven
			119
			112
			26
			12
Orange PSA scanned			6
at Hamden			79
Orange	150		3
New Haven	357	←	Essex PSA
W Haven	238		at Hamden
Milford	240		Essex
Woodbridge	112		Madison
Shelton	39		Clinton
Derby	29		Old Saybro
N Haven	291		Westbrook
E Haven	60		Old Lyme
Stratford	42		Deep River
	<u>1558</u>		Chester
			Guilford
			<u>29</u>
			73

EXHIBIT K

000194



Connecticut Orthopaedic Specialists

AND OUR DIVISIONS

The Orthopaedic Group

OrthopedicHealth



Center For Orthopaedics

SHORELINE

ORTHOPEDICS & SPORTS MEDICINE

2015 Shoreline (Essex) MRI Referrals by Town

ZIP Code	Town	MRI Referrals
06334	Bozarth, CT	1
06405	Branford, CT	3
06234	Brooklyn, CT	1
33904	Cape Coral, FL	1
06410	Cheshire, CT	1
06412	Chester, CT	40
06412	Clinton, CT	6
06415	Colchester, CT	4
06413	Cromwell, CT	100
06416	Deep River, CT	1
06422	Durham, CT	7
06419	East Haddam, CT	33
06423	East Haddam, CT	28
06420	East Hampton, CT	1
06424	East Hampton, CT	7
06333	East Lyme, CT	4
06357	East Lyme, CT	17
06029	Ellington, CT	1
06082	Enfield, CT	1
06409	Essex, CT	11
06426	Essex, CT	63
06442	Essex, CT	46
06032	Farmington, CT	1
06085	Farmington, CT	1
34994	Fort Myers, FL	1
06033	Glastonbury, CT	1
01034	Granville, MA	1
06340	Groton, CT	5
06437	Guilford, CT	13
06438	Haddam, CT	10
06441	Haddam, CT	12
06439	Haylyme, CT	6
06417	Killingworth, CT	69
06443	Madison, CT	64
06447	Marlborough, CT	1
06450	Meriden, CT	2
06455	Middlefield, CT	1
06457	Middletown, CT	11
06461	Milford, CT	1
06370	Montville, CT	2
06382	Montville, CT	1

ZIP Code	Town	MRI Referrals
06469	Moodus, CT	20
06355	Mystic, CT	1
06448	N/A	1
06513	New Haven, CT	1
06320	New London, CT	5
10016	New York, NY	1
10025	New York, NY	2
06471	North Branford, CT	1
06472	Northford, CT	2
06371	Old Lyme, CT	104
06376	Old Lyme, CT	3
06475	Old Saybrook, CT	141
33410	Palm Beach Gardens, FL	1
06480	Portland, CT	2
06375	Quaker Hill, CT	2
11377	Queens, NY	1
06067	Rock Hill, CT	1
06417	Salem, CT	1
06467	Southington, CT	1
06479	Southington, CT	1
06378	Stonington, CT	1
06066	Vernon, CT	1
27587	Wake Forest, NC	1
06492	Wallingford, CT	1
06706	Waterbury, CT	1
06385	Waterford, CT	9
06498	Westbrook, CT	77

000195

JNS

ITS MEDICINE

Essex	120	120
Madison	64	64
		6
Guilford	13	141
Clinton	6	77
Old Saybrook	141	107
Westbrook	77	1
Old Lyme	107	40
Deep River	1	556
Chester	40	
	569	

11
63
46
120

000196

EXHIBIT L

000197

Connecticut Orthopaedic Specialists

AND OUR DIVISIONS

The Orthopaedic Group OrthopedicHealth  Center For Orthopaedics **SHORELINE** ORTHOPEDICS & SPORTS MEDICINE

Ratio of the Number of MRI Scans to the Number of New Orthopaedic Patients Seen at COS

Location	# of New Patients	Estimated # of New Patients who Received MRI (15.6%)	# of Internal COS Scans	Estimated # of MRI External Referrals
Shelton 889 Bridgeport Ave	947	147	118	29
Orange 330 Boston Post Road	3675	573	567	6
Orange 464 Boston Post Road	376	58	20	38
Milford 30 Commerce Park	859	134	66	68
Milford 258 South Broad Street	1413	220	165	55
Milford 849 Boston Post Road	2285	356	105	251
Totals	9555	1488	1041	447

Ratio Exercise

Total number of new patients in 2015 across all locations/divisions = 29,303

Total number of new patients who received an MRI scan via a COS machine in 2015 = 4,589

Ratio 1:6.38 – 1 out of every 6.38 (15.6%) new patients seen in 2015 received an MRI scan via a COS machine

EXHIBIT M

000199



INTERNATIONAL, Inc.®

127 Ramah Circle • Agawam, MA 01001

Tel: 413-733-4828

Fax: 413-736-6369

Toll Free: 800-338-1287

Purchase Agreement

Contract # 061516-01

June 15, 2016

Page 1 of 3

Buyer:

Connecticut Orthopedic Specialist
 2408 Whitney Avenue
 Hamden, CT 06518

Attention: Glen Elia

Seller:

Med Exchange International, Inc.
 127 Ramah Circle
 Agawam, MA 01001

Attention: Steve Neffinger

Terms: A 50% deposit (\$287,500) is due upon acceptance of this agreement. An additional 30% payment (\$172,500) is due prior to installation. The final 20% payment (\$115,000) is due once the system is completely operational at the buyer's site.

Quantity	Products and Services	Price
	2000 Mobile GE 1.5T Excite (11x) 8 Channel MRI System AK Trailer 2007 ACGD Gradients Software Level: 11X Software Options: Echo planar, fast gradient echo, cine, fast gradient echo & flair, time of flight, phase contrast vascular imaging, SGD Echo Speed, DW EPI, Flair EPI, Special, Smart Prep, SSFSE, Three Plan Localizer, Modality Work list, e3dtof, FSX_XL, Blood supp, Fast Cine, iDrive pro, iDrive, Smart prep 2000 upgrade, probe 2000 upgrade, Func tool 2, Vox tool, interactive vascular imaging, Clairview, iDrive pro plus, ultra-short tr, ssfse mrcp, t1 breathhold, ACGD plus, Fluoro-triggered MRA, mrcp3, dynamic r1, fiesta 2d, fiesta 3d, asset, 3dfrfse, asset plus, tricks, fiesta-c, breast2, propeller dwi, 3d fat sat fiesta, propeller t2 Coil package: 3" round (2) GP Flex (2) 8 Channel Body 8 Channel CTL 8 Channel Neuro-Vascular 8 Channel Head Quad Head Quad Extremity	\$575,000.00



INTERNATIONAL, Inc.®

127 Ramah Circle • Agawam, MA 01001

Tel: 413-733-4828

Fax: 413-736-6369

Toll Free: 800-338-1287

Full 30 day all parts and labor warranty on system. Includes shipping of system to your location.

Buyer's Initials: _____ **Date:** _____

Seller's Initials: _____ **Date:** _____



INTERNATIONAL, Inc.®

127 Ramah Circle • Agawam, MA 01001

Tel: 413-733-4828

Fax: 413-736-6369

Toll Free: 800-338-1287

Page 3 of 3
Contract #061516-01
June 15, 2016

Sale will be on the following terms and conditions:

1. **Inspection.** The Equipment will have been inspected prior to the sale by the buyer to verify that the Equipment meets all OEM specifications for image quality and condition. The Equipment shall be deemed to be satisfactory upon certification by the inspector. Buyer shall be deemed to have accepted any nonconforming Equipment unless Buyer notifies Seller in writing within 24 hours of site inspection and discovery of any such nonconformity.
2. **Warranty.** Included in the price is the cost of a 30-day full coverage maintenance agreement with GE or a third party. The customer can choose the service provider that they wish to use. Med Exchange reserves the right to negotiate the cost of the contract.
3. **Taxes.** Prices do not include applicable sales, excise, use, value added or other taxes, duties or fees now in effect or hereafter levied which Seller may be required to pay or collect in connection with the sale of goods to the Buyer, whether or not expressly set forth herein or in any quotation furnished with respect to the Equipment. Buyer shall promptly pay all such taxes, duties and fees to Seller upon demand. Duties and fees include, but are not limited to, applicable customs duties and custom broker charges.
4. **Offer.** This offer is expressly limited to the terms hereof. The terms of this offer may not be modified or altered unless such modification is in writing, signed by Seller. Any additional or different terms purposed by Buyer are hereby rejected and will be of no effect upon Seller unless expressly agreed to in writing by authorized representative of Seller.
5. **Acceptance of Terms.** Buyer shall be deemed to have accepted the terms of this offer by signing below or by ordering the Equipment from Seller.
6. **Security Interest.** Buyer grants Seller a security in interest in the Equipment to secure payment in full of the purchase price. Seller may perfect its security interest by filing a financing statement signed only by Seller as attorney in fact for Buyer.
7. **Title and Risk of Loss.** Unless otherwise specified, the Equipment shall be delivered to Buyer F.O.B. shipping point. Title to goods shall pass to the Buyer upon delivery at the F.O.B. shipping point. Unless otherwise stated on the invoice, all shipping costs shall be the Buyer's responsibility.
8. **Governing Law.** The laws of the State of Massachusetts shall govern the enforcement and interpretation of this Agreement and all other issues concerning the sale contemplated herein. Buyer consents to the jurisdiction of Massachusetts courts and further agrees that the exclusive venue for any matter relating to payment for the Equipment shall be in the courts of Hampden County, Massachusetts.
9. **Default.** If Buyer fails to make timely payment of all amounts due Seller, Seller may recover, in addition to the balance due of the purchase price, all of its incidental and consequential damages caused by Buyer's breach, including all fees paid to collection agencies, attorney's fees, and costs of collection.
10. **Entire Contract.** This Agreement constitutes the entire contract between Buyer and Seller concerning the Equipment.

Buyer:

Seller:

By: _____

By: _____

Glen Elia
Connecticut Orthopedic Services

Steve Neffinger
Med Exchange International, Inc.

Date: _____

Date: _____



Kingsbrook
DEVELOPMENT CORP.

July 21, 2016

Mr. Glenn Elia, CEO
CONNECTICUT ORTHOPAEDIC SPECIALISTS, PC
2408 Whitney Avenue
Hamden, CT 06518

RE: MRI Trailer Installations - Essex & Orange Offices

Dear Glenn,

Per your request we completed an initial review for the installation of an MRI trailer at both of the above offices relative to building, parking and site layout for Project budget purposes. At this time, we have not met with Town/City officials to establish site specific requirements at each location as they will differ and this in itself is an actual project. Based on the aforementioned and our past experience of installations we established a Project budget which can be utilized for each site and as you can see Project cost will be directly attributed to required scopes at each location. Should these potential Projects move to the next Phase then it is our recommendation that a "Design Development" scope be initiated. Project Budget as follows:

Project Scope Establishment & Mobilization
Survey & Site Plan Approval
Site Work & Associated Pad/Paving Work
Landscaping & Associated Screening
Canopy & Walkway Enclosures
Building Power Upgrade & Associated Distribution Work.
Electrical Work & Interior Construction.

Project Budget \$135,000.00 - \$155,000

Thank you for the opportunity to review these Projects and should you have any questions please do not hesitate to contact me.

Respectfully submitted,
KINGSBROOK DEVELOPMENT CORP.

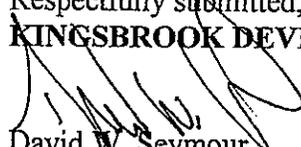

David W. Seymour
President

EXHIBIT N

000204



August 15, 2016

Connecticut Orthopaedic Specialists, PC
2408 Whitney Avenue
Hamden, CT 06518
Attention: Glenn Elia, CEO

Ladies and Gentlemen:

First Niagara Bank, N.A. is pleased to advise you that your application for a loan has been approved, subject to the following principal terms and conditions:

The terms of the credit facilities that Lender offers to commit to make available (individually a "Loan" or "Facility", collectively the "Loans" or the "Facilities") are as follows:

- I. LENDER: First Niagara Bank, N.A., a national banking association having an address of 726 Exchange Street, Buffalo, NY 14210, Attention: Commercial Loan Administration.
- II. BORROWER: Connecticut Orthopaedic Specialists, PC.
- III. GUARANTORS: The same as for the company's existing line of credit.
- IV. FACILITY/TERM LOAN:
 1. Amount: \$730,000.00.
 2. Term/Amortization: Sixty Months.
 3. Interest Rate: A fixed rate equal to the FHLBNY Rate, plus 2.00% per annum.
 4. Collateral: a first lien on all of Borrower's Assets and a purchase money lien on the MRI being financed.
 5. Use of Proceeds: Purchase of an MRI and leasehold improvements to accommodate it.
- V. LOAN TERMS APPLICABLE TO ALL FACILITIES:
 1. COLLATERAL PERFECTION: Liens on non-real estate collateral will be perfected by filing a UCC financing statement or as otherwise appropriate.
 2. CROSS-DEFAULT/CROSS COLLATERALIZE: All facilities will be cross-defaulted with all other debt of Borrower and cross-collateralized with all other existing and future indebtedness from Lender to Borrower
 3. REPORTING REQUIREMENTS: Borrower shall submit or require to be submitted Financial Statements and all other reporting requirements as required under their existing line of credit agreement.

All financial reports furnished to Lender will be prepared in accordance with GAAP, consistently applied, be in form and content satisfactory to Lender, certified to be true and correct by the party offering such statement, and include a representation that Lender may rely on such statements.

000205

Borrower and any Guarantor(s) will be required to comply with the above financial reporting requirements throughout the term or terms of the Facility. The documents evidencing and securing the Facility will provide that failure to comply with such requirements shall constitute an event of default under the Loan Documents.

CONDITION PRECEDENT: On or prior to the closing date, Borrower shall provide to Lender such items as shall be required by Lender.

CONDITIONS/COVENANTS: Usual and customary for loans of this size and duration

INSURANCE: Borrower shall at all times keep all of Borrower's assets that are pledged as collateral for the Facility(ies) insured against such hazards and in such amounts satisfactory to Lender, naming Lender as Lender Loss Payee and/or Mortgagee and as Additional Insured at Lender's address as follows: First Niagara Bank, N.A. ISAOA, P.O. Box 514, Lockport, NY 14095-0514, Attention: Enterprise Insurance Tracking. Borrower shall as a condition to closing and at least annually thereafter submit to Lender, on or prior to the anniversary of the Loans, certificates of such insurance issued to Lender and its successors and/or assigns, together with evidence of payment of premiums for such insurance.

PAYMENT ALLOCATION: Unless otherwise specified in the Loan Documents, Lender reserves the right to apply payments at its discretion.

LOAN DOCUMENTS: This letter includes only a brief description of the principal terms of the Facility. The definitive terms of the Facility will be documented in the Loan Documents. Borrower shall execute and deliver to Lender credit and loan documentation evidencing and securing the Facility(ies) in form and substance satisfactory to Lender and its counsel (collectively, the "Loan Documents") containing such representations, warranties, conditions, covenants, defaults and remedies as are customary in transactions of similar type to the Facility. Other conditions precedent to closing the Loans will include, but are not limited to, lien searches with results acceptable to Lender, and completion of Lender's due diligence which is satisfactory to Lender.

NO SURVIVAL: It is understood that the terms and conditions of this letter shall not survive the execution and delivery of the Loan Documents except that all indemnities and reimbursement obligations shall survive any such termination.

EXPENSES AND INDEMNIFICATION: By its acceptance of this letter, Borrower agrees to pay or cause to be paid at or before the closing all charges and fees in connection with the Facility(ies), including and not by way of limitation, the fees and disbursements of Lender's counsel (including outside and internal counsel). Borrower shall pay any and all costs associated with Lender (1) performing or ordering any searches or updates of Borrower, credit history or the collateral, or (2) Lender preparing, terminating, discharging or assigning any of its Loan Documents. If the closing does not take place for any reason, except for Lender's willful refusal to make the Loan, Borrower will be obligated to pay upon demand all of Lender's out-of-pocket fees and expenses in connection with the transactions contemplated by this letter, including, without limitation, fees and expenses of Lender's counsel. Borrower hereby indemnifies and holds Lender and its employees, agents, directors and affiliates harmless from and against any and all losses, claims, damages, expenses and liabilities incurred that arise out of or relate to this letter or the transaction contemplated hereby, including, without limitation, reasonable fees and expenses of Lender's counsel. Lender shall not be responsible or liable to Borrower or any other person for any damages, consequential or otherwise, which may be incurred or alleged as a result of this letter or the transaction, and Borrower's obligations shall survive any termination of this letter except for the execution of definitive Loan Documents.

WAIVER OR MODIFICATION: The provisions of this letter cannot be waived or modified unless such waiver or modification is in writing and signed by Lender.

RIGHT TO REFUSE TO CLOSE: Lender reserves the right to refuse to make the Facility available (which is not willful refusal) if (1) there is any material adverse change in the financial condition or assets of Borrower or any Guarantor; (2) any of the transactions contemplated by this letter would violate any governmental rule, regulation or statute in force at the time of the closing; (3) any of the information submitted by Borrower or any Guarantor to Lender is false, incomplete or inaccurate in any material respect; or (4) the conditions of this letter are not satisfied prior to its expiration.

000206

CONFIDENTIALITY OF COMMITMENT: This letter and the terms hereof are confidential, and neither the contents of this letter nor the details hereof may be shown or disclosed by Borrower without the prior express written consent of Lender.

ENTIRE AGREEMENT: This letter constitutes the entire agreement and understanding between Lender and Borrower with respect to the Facilities and supersedes all prior negotiations, understandings and agreements between such parties with respect to the terms hereof, including, without limitations, those expressed in any prior proposal, term sheet or commitment letter delivered by Lender to Borrower.

APPLICABLE LAW: This letter, and the transactions contemplated hereby or arising hereunder, shall be construed under and governed by the laws of the State of Connecticut, without regard to principles of conflicts of laws. The Loan documentation will contain (1) consents to jurisdiction, (2) waiver of right to jury trial, and (3) prejudgment remedy waiver. This letter shall be interpreted and the rights and liabilities of the parties shall be governed by the laws of the State of Connecticut, without regard to principles of the conflict of laws. This letter has been delivered to and accepted by Lender and will be deemed to be made in the State of Connecticut.

If this offer is acceptable, please indicate your acceptance by signing and returning the enclosed copy of this letter. We look forward to working with you on successfully completing this transaction. We will begin documenting the credit after we have received your signed copy of this letter.

[SIGNATURE PAGE FOLLOWS.]

000207

Very truly yours,

FIRST NIAGARA BANK, N.A.

By: 
Name: Peter J. Thomas
Its: First Vice President

Enclosure

Accepted and agreed to this 16 day of August, 2016
with the intent to be legally bound hereby.

Connecticut Orthopaedic Specialists, PC
(Borrower)

By: 
Name: CLEMELIA
Its: CEO

000208

EXHIBIT O

000209

To the Board of Directors
Connecticut Orthopaedic Specialists, PC
Hamden, CT

Management is responsible for the accompanying financial statements of Connecticut Orthopaedic Specialists, PC, which comprise the balance sheets as of December 31, 2015 and 2014, and the related income statements, for the years ended December 31, 2015 and 2014, and for determining that the income tax basis of accounting is an acceptable financial reporting framework. We have performed a compilation engagement in accordance with Statements on Standards for Accounting and Review Services promulgated by the Accounting and Review Services Committee of the AICPA. We did not audit or review the financial statements nor were we required to perform any procedures to verify the accuracy or completeness of the information provided by management. Accordingly, we do not express an opinion, a conclusion, nor provide any form of assurance on these financial statements.

The financial statements are prepared in accordance with the income tax basis of accounting, which is a basis of accounting other than accounting principles generally accepted in the United States of America.

Management has elected to omit substantially all of the disclosures and the statement of cash flows ordinarily included in financial statements prepared in accordance with the income tax basis of accounting. If the omitted disclosures were included in the financial statements, they might influence the user's conclusions about the Company's assets, liabilities, stockholders' equity, revenues, and expenses. Accordingly, the financial statements are not designed for those who are not informed about such matters.

Woodbridge, Connecticut

Teplitzky & Co. PC

August 1, 2016

Connecticut Orthopaedic Specialists, PC
Balance Sheets
December 31, 2015 and 2014

	2015	2014
<u>ASSETS</u>		
Current Assets		
Cash	\$ 1,490,210	\$ 1,499,747
Due from COS Outpatient Surgical Center, LLC	552,003	298,945
Due from TPT, LLC	59,775	59,775
Due from Center for Orthopedics	965,941	-
Fixed Asset Construction in Progress	-	345,291
Total Current Assets	3,067,929	2,203,758
Accounts Receivable		
Patient Accounts Receivable	31,208,585	18,110,020
Allowance for uncollectible accounts	(4,802,859)	(1,247,537)
Net Accounts Receivable	26,405,726	16,862,483
Fixed Assets		
Furniture, Fixtures & Equipment	3,728,272	3,449,344
Leasehold Improvements	2,744,370	2,720,931
Software & Licenses	1,116,634	242,758
Other Intangibles	13,977	13,977
Total Fixed Assets	7,603,253	6,427,010
Accumulated Depreciation	(3,926,041)	(3,548,041)
Net Fixed Assets	3,677,212	2,878,969
Other Assets		
Investment in COS Outpatient Surgical Center, LLC	546,723	414,557
Note Receivable - S. Tomak	146,447	146,447
Life Insurance - Cash Surrender Value, net	-	298,421
Security Deposit	10,619	10,619
Total Other Assets	703,789	870,044
Total Assets	\$ 33,854,656	\$ 22,815,254

See independent accountant's compilation report.

Connecticut Orthopaedic Specialists, PC
Income Statements
For the Years Ended December 31, 2015 and 2014

	<u>2015</u>	<u>%</u>	<u>2014</u>	<u>%</u>	<u>Change</u>
Revenue					
Gross Charges	\$ 218,511,430	100.00	\$ 144,566,534	100.00	\$ 73,944,896
Billing Adjustments	(143,911,628)	(65.86)	(93,546,858)	(64.71)	(50,364,770)
Net Revenue	<u>74,599,802</u>	<u>34.14</u>	<u>51,019,676</u>	<u>35.29</u>	<u>23,580,126</u>
Cost of Revenues					
Medical Supplies	3,322,935	1.52	2,626,385	1.82	696,550
X-Ray Supplies	46,335	0.02	20,817	0.01	25,518
Physical Therapy Supplies	134,505	0.06	129,740	0.09	4,765
Anesthesia Services	1,469,600	0.67	1,481,455	1.02	(11,855)
Total Cost of Revenues	<u>4,973,375</u>	<u>2.28</u>	<u>4,258,397</u>	<u>2.95</u>	<u>714,978</u>
Gross Profit	<u>69,626,427</u>	<u>31.86</u>	<u>46,761,279</u>	<u>32.35</u>	<u>22,865,148</u>
Operating Expenses					
Salaries - Officers	19,704,054	9.02	17,592,498	12.17	2,111,556
Salaries	23,921,787	10.95	17,933,550	12.41	5,988,237
Administrative Management Fees	324,169	0.15	778,889	0.54	(454,720)
Repairs & Maintenance	156,704	0.07	128,823	0.09	27,881
Rents	2,822,250	1.29	1,804,023	1.25	1,018,227
Payroll Taxes	2,441,955	1.12	1,727,023	1.19	714,932
Property Tax	119,786	0.05	83,827	0.06	35,959
Miscellaneous Taxes	1,268	0.00	5,708	0.00	(4,440)
Interest	130,506	0.06	137,156	0.09	(6,650)
Depreciation	378,000	0.17	680,594	0.47	(302,594)
Advertising	551,558	0.25	500,879	0.35	50,679
Pension	2,566,823	1.17	1,735,175	1.20	831,648
Meals & Entertainment	129,212	0.06	87,167	0.06	42,045
Answering Service	53,283	0.02	38,143	0.03	15,140
Auto Reimbursement	587,792	0.27	553,801	0.38	33,991
Less: Auto Add-Back	-	-	(96,600)	(0.07)	96,600
Bank Charges	228,973	0.10	119,361	0.08	109,612
Cleaning	290,341	0.13	154,488	0.11	135,853
Computer Expenses	1,251,750	0.57	593,791	0.41	657,959
Dues	151,435	0.07	118,755	0.08	32,680
Equipment Lease	534,911	0.24	271,536	0.19	263,375
Health Insurance	1,782,934	0.82	1,656,384	1.15	126,550
Insurance	667,093	0.31	219,493	0.15	447,600
Licenses	48,954	0.02	47,709	0.03	1,245
Malpractice Insurance	703,731	0.32	796,113	0.55	(92,382)
Meetings	42,571	0.02	83,849	0.06	(41,278)
Office Supplies	221,460	0.10	142,878	0.10	78,582
Outside Services	1,973,065	0.90	821,414	0.57	1,151,651
Parking	19,211	0.01	10,810	0.01	8,401
Patient Gifts	80,081	0.04	54,621	0.04	25,460
Payroll Processing	61,723	0.03	41,252	0.03	20,471
Postage	89,916	0.04	76,895	0.05	13,021
Professional Development	259,673	0.12	223,246	0.15	36,427

See independent accountant's compilation report.

Connecticut Orthopaedic Specialists, PC
Balance Sheets
December 31, 2015 and 2014

	2015	2014
<u>LIABILITIES & STOCKHOLDERS' EQUITY</u>		
Current Liabilities		
Accounts Payable	\$ 1,946,798	\$ 1,776,810
Accrued Profit Sharing	2,566,823	1,735,176
Accrued Payroll and Tax Related Expenses	5,954	832
Due to the Orthopaedic Group	-	778,889
Due to Lieponis	-	19,000
Total Current Liabilities	4,519,575	4,310,707
Notes Payable		
Line of Credit - Center for Orthopaedics	798,403	-
Notes Payable - First Niagara	3,000,295	2,691,832
MRI Loan	27,495	106,763
Notes Payable - Physicians	735,353	214,063
Total Notes Payable	4,561,546	3,012,658
Total Liabilities	9,081,121	7,323,365
Stockholders' Equity		
Common Stock	3,080	3,080
Paid in Capital	415,777	400,777
Retained Earnings	24,354,678	15,088,032
Total Stockholders' Equity	24,773,535	15,491,889
Total Liabilities & Stockholders' Equity	\$ 33,854,656	\$ 22,815,254

See independent accountant's compilation report.

Connecticut Orthopaedic Specialists, PC
Income Statements
For the Years Ended December 31, 2015 and 2014

	<u>2015</u>	<u>%</u>	<u>2014</u>	<u>%</u>	<u>Change</u>
Operating Expenses (continued)					
Professional Fees	\$ 319,957	0.15	\$ 327,956	0.23	\$ (7,999)
Refuse	6,423	0.00	5,935	0.00	488
Service Agreement	203,231	0.09	163,231	0.11	40,000
Stationary & Printing	56,485	0.03	36,642	0.03	19,843
Subscriptions	49,058	0.02	16,639	0.01	32,419
Telephone	178,374	0.08	136,626	0.09	41,748
Transcription	433,732	0.20	389,802	0.27	43,930
Uniforms	14,951	0.01	16,142	0.01	(1,191)
Utilities	404,808	0.19	267,488	0.19	137,320
Total Operating Expenses	<u>63,963,988</u>	<u>29.27</u>	<u>50,483,712</u>	<u>34.92</u>	<u>13,480,276</u>
Other Income					
Interest Income	378	0.00	6,114	0.00	(5,736)
Income from COS Surgical Center, LLC	3,595,191	1.65	418,056	0.29	3,177,135
Gain on sale of assets	8,638	0.00	3,939,647	2.73	(3,931,009)
Total Other Income	<u>3,604,207</u>	<u>1.65</u>	<u>4,363,817</u>	<u>3.02</u>	<u>(759,610)</u>
Net Income	<u>\$ 9,266,646</u>	<u>4.24</u>	<u>\$ 641,384</u>	<u>0.44</u>	<u>\$ 8,625,262</u>

See independent accountant's compilation report.

EXHIBIT P

000214

Applicant Name: Connecticut Orthopaedic Specialties
 Financial Worksheet (B)
 without, incremental to and with the CON proposal in the following reporting format:

FOR PROFIT

Year of actual results and three years of projections of Total Entity revenue, expense and volume statistics

LINE	Description	FY (1)		FY (2)		FY (3)		FY (4)		FY (5)		FY (6)		FY (7)		FY (8)		FY (9)		FY (10)		FY (11)		FY (12)		FY (13)				
		Actual Results	Projected	Without CON	Incremental	Without CON	Incremental	Without CON	Incremental	Without CON	Incremental	Without CON	Incremental	Without CON	Incremental	Without CON	Incremental	Without CON	Incremental	Without CON	Incremental	Without CON	Incremental	Without CON	Incremental	Without CON	Incremental	Without CON	Incremental	
A. OPERATING REVENUE																														
1	Total Gross Patient Revenue	\$1,578,830	\$14,200,220	\$0	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	
2	Less: Allowances	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	
3	Less: Charity/Care	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	
4	Less: Other Deductions	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	
5	Net Patient Service Revenue	\$1,578,830	\$14,200,220	\$0	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	\$14,200,220	\$0	
B. OPERATING EXPENSES																														
1	Salaries and Wages	\$670,318	\$743,874	\$191,202	\$0	\$191,202	\$0	\$191,202	\$0	\$191,202	\$0	\$191,202	\$0	\$191,202	\$0	\$191,202	\$0	\$191,202	\$0	\$191,202	\$0	\$191,202	\$0	\$191,202	\$0	\$191,202	\$0	\$191,202	\$0	\$191,202
2	Fringe Benefits	\$81,286	\$89,302	\$22,164	\$0	\$22,164	\$0	\$22,164	\$0	\$22,164	\$0	\$22,164	\$0	\$22,164	\$0	\$22,164	\$0	\$22,164	\$0	\$22,164	\$0	\$22,164	\$0	\$22,164	\$0	\$22,164	\$0	\$22,164	\$0	\$22,164
3	Presidents Fees	\$599,300	\$677,800	\$77,500	\$0	\$77,500	\$0	\$77,500	\$0	\$77,500	\$0	\$77,500	\$0	\$77,500	\$0	\$77,500	\$0	\$77,500	\$0	\$77,500	\$0	\$77,500	\$0	\$77,500	\$0	\$77,500	\$0	\$77,500	\$0	\$77,500
4	Supplies and Drugs	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	
5	Depreciation and Amortization	\$92,188	\$92,188	\$0	\$0	\$92,188	\$0	\$92,188	\$0	\$92,188	\$0	\$92,188	\$0	\$92,188	\$0	\$92,188	\$0	\$92,188	\$0	\$92,188	\$0	\$92,188	\$0	\$92,188	\$0	\$92,188	\$0	\$92,188	\$0	\$92,188
6	Provision for Bad Debt/Other*	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	
7	Interest Expense	\$13,156	\$13,156	\$0	\$0	\$13,156	\$0	\$13,156	\$0	\$13,156	\$0	\$13,156	\$0	\$13,156	\$0	\$13,156	\$0	\$13,156	\$0	\$13,156	\$0	\$13,156	\$0	\$13,156	\$0	\$13,156	\$0	\$13,156	\$0	\$13,156
8	Malpractice Insurance Cost	\$30,070	\$30,070	\$0	\$0	\$30,070	\$0	\$30,070	\$0	\$30,070	\$0	\$30,070	\$0	\$30,070	\$0	\$30,070	\$0	\$30,070	\$0	\$30,070	\$0	\$30,070	\$0	\$30,070	\$0	\$30,070	\$0	\$30,070	\$0	\$30,070
9	Lease Expense	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
10	Other Operating Expenses	\$1,333,252	\$1,479,643	\$146,391	\$0	\$146,391	\$0	\$146,391	\$0	\$146,391	\$0	\$146,391	\$0	\$146,391	\$0	\$146,391	\$0	\$146,391	\$0	\$146,391	\$0	\$146,391	\$0	\$146,391	\$0	\$146,391	\$0	\$146,391	\$0	\$146,391
	TOTAL OPERATING EXPENSES	\$2,828,580	\$3,233,733	\$419,655	\$0	\$419,655	\$0	\$419,655	\$0	\$419,655	\$0	\$419,655	\$0	\$419,655	\$0	\$419,655	\$0	\$419,655	\$0	\$419,655	\$0	\$419,655	\$0	\$419,655	\$0	\$419,655	\$0	\$419,655	\$0	\$419,655
	INCOME/LOSS FROM OPERATIONS	\$1,849,618	\$2,309,932	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798
	NON-OPERATING INCOME	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	
	Income before provision for income taxes	\$1,849,618	\$2,309,932	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798
	Provision for income taxes*	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	
	NET INCOME	\$1,849,618	\$2,309,932	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798	\$0	\$2,205,798
C. RETAINED EARNINGS, BEGINNING OF YEAR																														
	Retained Earnings, beginning of year	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	
D. PROFITABILITY SUMMARY																														
1	Hospital Operating Margin	39.5%	41.7%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%
2	Hospital Non-Operating Margin	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
3	Hospital Total Margin	39.5%	41.7%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%	0.0%	41.2%
E. FTEs																														
1	FTEs	11	12	12	0	12	0	12	0	12	0	12	0	12	0	12	0	12	0	12	0	12	0	12	0	12	0	12	0	12
F. VOLUME STATISTICS*																														
1	Inpatient Discharges	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	Outpatient Visits	7,624	9,214	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214
	TOTAL VOLUME	7,624	9,214	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214	0	9,214

Total amount should equal the total amount on call line #16 Patient Revenue Row 14.
 Provide the amount of any transaction associated with Bad Debts not related to the provision of direct services to patients. For additional information, refer to FASB, No.2011-07, July 2011.
 Provide the amount of income taxes as defined by the Internal Revenue Services for for-profit entities.
 Provide projected inpatient and/or outpatient statistics for any new services and provide actual and projected inpatient and/or outpatient statistics for any existing services which will change due to the proposal.

EXHIBIT Q

000216

Assumptions for Financial Worksheet

Revenue assumptions

Without the new mobile scanner, assume number of scans would remain constant from 2016 levels since both existing scanners are at nearly full capacity.

Utilized payer mix assumptions for number of scans and 2015 per scan reimbursements by payer.

Salaries & Wages

Includes MRI technicians, support staff and authorizations staff as well as supervisor for business unit. Assume addition of 1 staff member during 2016 to support extended hours and authorizations for additional scans. Assume 3% annual cost of living increases for existing staff. With addition of new unit to be utilized in Essex and Orange, 2.0 FTE's would be added to support additional locations.

Fringe benefits

Includes payroll taxes, health and dental coverage for staff members, disability and life insurance and retirement plan contributions.

Physician fees

Includes radiologist expense based on annual number of scans.

Depreciation and amortization

Includes depreciation expense for existing units. Assumes addition of 5 year depreciation on capital expenditure of \$730,000 for purchase of new unit and installation costs.

Interest expense

Includes interest on existing two units. Projected incremental assumes 4% interest rate on \$730,000 loan for purchase of additional unit and installation.

Malpractice Expense

Includes malpractice expense for two radiologists supporting MRI units.

Other Operating Expenses

000217

Includes rent, utilities, property taxes and other real estate operating costs for existing equipment and locations.

Includes equipment maintenance expenses as well as repairs and maintenance for locations.

Includes IT support expenses, and office supplies expense as well as billing and collections staff and corporate administrative support including accounting, human resources and management team supervision.

Without the proposal, and not taking into account any increase for inflation, it is assumed that 2017 levels of the items listed above will remain constant with the exception of billing and collections expense, which will increase based on volume of scans. Projected incremental increases also includes moving expense for mobile unit, two moves per week.

Greer, Leslie

From: Fernandes, David
Sent: Wednesday, September 21, 2016 3:28 PM
To: gelia@ct-ortho.com
Cc: Greer, Leslie; Riggott, Kaila
Subject: 16-32117-CON Completeness Letter
Attachments: 16-32117-Completeness Letter 2.docx

Good afternoon Mr. Elia,

Please see the attached completeness letter in the matter of the proposed acquisition of a mobile 1.5 Tesla MRI by Connecticut Orthopedic Specialists. In responding to the completeness letter questions, please follow the instructions included in the letter and provide the response document as an attachment only (no hard copies required). Please provide your written responses to OHCA by November 20, 2016.

Email to OHCA@ct.gov and cc: David.Fernandes@ct.gov and Kaila.Riggott@ct.gov.

If you have any questions regarding the completeness letter, please contact David Fernandes (860) 418-7032 or Kaila Riggott at (860) 418-7037.

Please confirm receipt of this email.

Thank You,

David Fernandes

Planning Analyst (CCT)
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, Hartford, Connecticut 06134
P: (860) 418-7032 | F: (860) 418-7053 | E: David.Fernandes@ct.gov



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH



Raul Pino, M.D., M.P.H.
Acting Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

September 21, 2016

VIA EMAIL ONLY

Mr. Glenn F. Elia
Chief Executive Officer
Connecticut Orthopedic Specialists, P.C.
2408 Whitney Avenue
Hamden, CT 06518

RE: Certificate of Need Application; Docket Number: 16-32117-CON
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner
Completeness Letter

Dear Mr. Elia:

On August 22, 2016, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application filing on behalf of Connecticut Orthopedic Specialist, P.C. ("COS"). This proposal requests authorization to acquire a mobile 1.5 Tesla MRI unit with an associated capital expenditure of \$760,000.

OHCA requests additional information pursuant to Connecticut General Statutes §19a-639a(c). *Please electronically confirm receipt of this email as soon as you receive it.* Provide responses to the questions below in both a Word document and PDF format at the earliest convenience as an attachment to a responding email. **Please email your responses to all of the following email addresses: OHCA@ct.gov, David.Fernandes@ct.gov, and Kaila.Riggott@ct.gov.**

Pursuant to Section 19a-639a(c) of the Connecticut General Statutes, you must submit your response to this request for additional information no later than sixty days after the date that this request was transmitted. Therefore, please provide your written responses to OHCA no later than **November 20, 2016**, otherwise your application will be automatically considered withdrawn.



Phone: (860) 509-8000 • Fax: (860) 509-7184 • VP: (860) 899-1611
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
www.ct.gov/dph

Affirmative Action/Equal Opportunity Employer

Paginate and date your response (i.e., each page in its entirety). Repeat each OHCA question before providing your response. Information filed after the initial CON application submission (e.g., completeness response letter, prefiled testimony, late file submissions, etc.) must be numbered sequentially from the Applicant’s preceding document. Begin your submission using **Page 218** and reference “**Docket Number: 16-32117-CON.**”

1. Page 18 of the application states that COS orthopedic offices in the Essex area have to refer patients to other providers for MRI services due to not being able to accommodate the volume. Please provide information regarding the referrals using the tables below. Please specify the fiscal year in which the referrals were made.

Fiscal Year:	Essex Service Area	
Provider Name and Address	Number of Patients Referred	Distance from Essex
Total		

2. How will accessibility be improved as stated on page 19 of the application if current MRI volume is being met by other area providers?
3. Who will staff the mobile MRI? Will the staff be the same for both locations?
4. On average, how much of a savings (with the advent of bundled payments versus traditional billing practices) have patients seen? Please quantify if possible and explain how patient savings are attained.
5. Provide the percentage of patients with insurance plans that accept bundled payments versus traditional billing practices.
6. How will the addition of a mobile MRI scanner in Orange and Essex improve the quality of health care for the Medicaid population?
7. Please explain why the equipment cost shown on Table 3 (p. 41) is not included in the total project cost and why the total expenditure does not match the expenditure in the newspaper notice (p. 5).
8. Why was there a drop in MRI volume at the Branford facility in FY2013?
9. Why was FY2015 the sole year used to project the service area given that Branford volume was significantly lower the previous three years?
10. Please provide articles or patient satisfaction surveys that demonstrate the quality of a mobile MRI.
11. How would the operation of the proposed mobile MRI conform to the intent of federal law? (Stark).

If you have any questions concerning this letter, please feel free to contact me at (860) 418-7032, or Kaila Riggott at (860) 418-7037.

Greer, Leslie

From: Glenn F. Elia <gelia@ct-ortho.com>
Sent: Tuesday, November 08, 2016 2:17 PM
To: User, OHCA; Fernandes, David; Riggott, Kaila; 'klg1@aol.com'
Subject: OCHA Docket No. 16-32117- CON Completeness Responses
Attachments: COS Completeness Answers 11.3.16.docx; Exhibit R.pdf; Combined Docs 11.3.16.pdf

Dear Ms. Riggott and Mr. Fernandez:

Attached please find the word version of the COS Responses to OHCA's Completeness Questions which were dated September 21, 2016 and a copy of Exhibit R. A copy of the completeness responses in pdf format is also attached, which consists of the responses, a revised Index, a cover sheet for Exhibit R, and the pdf version of the Exhibit R.

Please note that I have copied, Attorney Pat Gerner in on this email. I would appreciate it if Attorney Gerner could be included in all future communication between COS & OCHA regarding this application.

Please let me know if you need anything further. Thank you.

Best regards,

Glenn Elia, CEO
Connecticut Orthopaedic Specialists, P.C.

Connecticut Orthopaedic Specialists, P.C.
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner
Docket Number 16-32117-CON
Completeness Questions Responses

- Page 18 of the application states that COS orthopedic offices in the Essex area have to refer patients to other providers for MRI services due to not being able to accommodate the volume. Please provide information regarding the referrals using the tables below. Please specify the fiscal year in which the referrals were made.

Essex Service Area

Fiscal Year: 2015

Provider Name and Address	Number of Patients Referred	Distance from Essex
Middlesex Hospital dba Shoreline Medical Center ED 250 Flat Rock Place Westbrook, CT 06498	639	4.5 miles
Middlesex Hospital Outpatient Center 534 Saybrook Road Middletown, CT 06457	78	19 miles
Middlesex Hospital 28 Crescent Street Middletown, CT 06457	49	22 miles
Open MRI of Middletown 140 Main Street #7 Middletown, CT 06457	48	22 miles
Guilford Radiology 1591 Boston Post Road 106 Guilford, CT 06437	29	18 miles
Groton MRI 565 Long Hill Road Groton, CT 06340	11	23 miles
Middlesex Hospital dba Marlborough Medical Center 12 Jones Hollow Road Marlborough, CT 06447	5	26 miles
Yale MRI 801 Howard Avenue New Haven, CT 06510	6	30.7 miles
Lawrence and Memorial 196 Waterford Parkway S # 102 Waterford, CT 06385	3	17 miles
Radiology Associates of Wallingford 67 Masonic Avenue #7 Wallingford, CT 06492	3	41 miles

Provider Name and Address	Number of Patients Referred	Distance from Essex
Jefferson Radiology 1260 Silas Dean Highway Wethersfield, CT 06109	5	31 miles
Radiology Associates of Middletown 57 S Main Middletown, CT 06457	4	23 miles
Open MRI of Branford 1208 Main Street Branford, CT 06405	3	24 miles
Open MRI of Glastonbury 123 Hebron Avenue Glastonbury, CT 06033	3	36 miles
Radiology Associates of Hartford 31 Sycamore Street #102 Glastonbury, CT 06033	2	27.5 miles
Whitney Imaging 2200 Whitney Avenue #120 Hamden, CT 06518	1	38 miles
Backus Hospital 326 Washington Street Norwich, CT 06360	1	30 miles
Day Kimball Hospital 320 Pomfret Street Putnam, CT 06260	1	63 miles
Naugatuck Valley Radiology 1389 West Main Street Waterbury, CT 06708	1	46 miles
Hartford Hospital 85 Seymour Street #200 Hartford, CT 06106	1	38 miles
Madison Radiology 2 Samson Park Drive Madison, CT 06443	1	13 miles
MRI of New Britain 100 Grand Street New Britain, CT 06052	1	34 miles
St. Francis MRI 114 Woodland Street Hartford, CT 06106	1	39 miles
Manhattan Diagnostic Radiology 400 E 66 Street New York, NY 10066	1	104 miles

The above table provides information for all patients (951) who were referred by Shoreline Orthopedic and Sports Medicine to a non-COS MRI scanner in 2015. Please note that this information could not be extracted electronically from the medical records, and was compiled manually from each patient record. As a result, there is a 12 person difference between the total number of patients reported here and what was reported in Exhibit L of the CON application (963).

2. How will accessibility be improved as stated on page 19 of the application if current MRI volume is being met by other area providers?

Accessibility is more than just having an open time slot in another MRI provider schedule. COS improves our patient accessibility by working directly with each patient to accommodate to their personal schedule. COS has early morning hours at 7 am so patients can be seen before work and they are open until 9 pm for after work hours. Likewise, if a patient cannot be seen during the week, COS will open on a weekend to accommodate the patient. If a patient presents with an acute injury and there is an emergent need for MRI, COS holds daily stat slots to accommodate these patients, again providing improved accessibility over traditional radiology centers. If the patient is in pain or in a position where the injury is made worse by moving around, traveling to another office creates a situation where having the MRI scan at a different location is not as accessible as walking (or being wheeled) down a hallway within the COS office to have the MRI performed. The time delay is also a factor, as orthopedic treatment should be administered as early as possible after the injury.

Currently almost all of the patients from the Shoreline Orthopedics and Sports Medicine offices of COS, and many of the patients from the 6 COS offices in Orange, Milford and Shelton are referred to non-COS providers for MRI scans. This is due to lack of capacity of the existing scanners in Hamden and Branford, and the geographic distance of these COS scanners from the Shoreline Orthopedic offices. Accessibility will be improved because the COS patients who use the proposed 1.5T mobile MRI will be able to have the MRI scan performed in the doctor's office without having to schedule and travel to another location and without waiting longer for the results.

3. Who will staff the mobile MRI? Will the staff be the same at both locations?

One FTE receptionist and 1 FTE MRI tech will be required for services provided in the mobile MRI unit. It is anticipated that both the receptionist and MRI tech will travel to both locations. Both the receptionist and the MRI tech will be COS employees. COS will continue to utilize Dr. Joseph Gagliardi as our radiologist to read the MRI studies in the two additional locations.

4. On average, how much of a savings (with the advent of bundled payments versus traditional billing practices) have patients seen? Please quantify if possible and explain how patient savings are attained.

In numerous locations in the above-referenced CON application, the method of "bundled payments" is discussed. COS has a bundled payment program with 3 major payors for outpatient reconstructive of both total knees and hips, and is working to include all of its payors in this program.

There is a correction that needs to be brought to the attention of OHCA which was only recently discovered as the applicant prepared for OHCA's Completeness Answers. The bundled payment program does not yet include the cost of the MRI. The MRI is often utilized as part of the diagnosis, and currently the bundled payment program does not begin until the injury is diagnosed and treatment begins. As both COS and the payor community become more familiar with the intricacies of bundled payment reimbursement, which includes the collection of data for post-operative complications

and patient outcomes, it is anticipated that more services (including MRI), can be included into the bundle. As both COS and the payor community become more familiar with the intricacies of bundled payments as well as further transformation from fee for service to value based reimbursement, it is anticipated that more services, including MRI will be included in risk based payment models. As the bundle becomes more complete, with both pre-operative and post-operative services, the risk sharing between provider and payor will allow for even greater savings to the delivery system.

The existing bundled payment plan already reduces the cost for the patient and payor. The efficiency of the outpatient total joint procedures (i.e., total hip and knee replacements) has allowed the payor to lower patient deductibles associated with inpatient procedures while lowering the total cost of the surgical event by several thousands dollars as compared to the same procedure done on an inpatient basis. The savings to the patient and the payor that are incurred for these procedures are as follows:

Pre- op visit	\$50
Home visit assessment	\$250
Physical therapy 16 visits @ \$35 / visit	\$560
ASC deductible or co insurance	\$3,000
Professional fee deductible or co insurance	\$1,995
Anesthesia fee deductible or co insurance	\$1,020
Pain block fee deductible or co insurance	\$420
DME deductible or co insurance	<u>\$100</u>
TOTAL	\$7,395

5. Provide the percentage of patients with insurance plans that accept bundled payments versus traditional billing practices.

Presently, the patients in COS who are under the bundled payment program make up approximately 3%. This is due to the fact that bundled payment programs are new and COS is the only practice in CT that is providing outpatient total joint procedures under a bundled payment arrangement. As healthcare reimbursement transitions from fee for service to pay for performance, capitations and bundled payment programs, it is anticipated that the percentage will increase in a dramatic fashion.

6. How will the addition of a mobile MRI scanner in Orange and Essex improve the quality of health care for the Medicaid population?

COS accepts Medicaid recipients at all of its offices and facilities; COS does not discriminate patients based on insurance type or ability to pay. The availability of MRI service in Orange and Essex at the physicians' offices will enhance the ability of all patients to access this necessary diagnostic modality. The MRI service is managed by Dr. Gagliardi, a board certified radiologist, who is able to read the MRI scan and report the findings back to the treating physician within the same day, but no later than 24 hours after the scan. The short time between the MRI scanning and the orthopedic physician's ability to start treatment makes an enormous difference in the quality of health care provided. While this service will only be available two days a week in both locations, it will allow more COS patients (Medicaid and all others) to take advantage of a seamless health care service.

7. Please explain why the equipment cost shown on Table 3 (p. 41) is not included in the total project cost and why the total expenditure does not match the expenditure in the newspaper notice (p. 5).

The estimated costs for the installation of the MRI trailer at the Orange and Essex locations were revised subsequent to the publication of the newspaper notice which listed a capital expenditure of \$675,000. At the time of the publication the installation costs were projected to be \$100,000 and the revised estimate increased the costs by \$35,000 to \$55,000. Therefore, the costs now range from \$135,000 to \$155,000. We have used the higher installation estimate in projecting the project costs. Additionally, a clerical error occurred in the completion of Table 3 as submitted in the CON application. The corrected Table 3 follows. Copies of the purchase agreement for the MRI unit and trailer with MedExchange International, Inc., and an estimate for the trailer installation by Kingsbrook Development Corp. are found in Exhibit M of the CON application, starting on page 199.

**REVISED TABLE 3
TOTAL PROPOSAL CAPITAL EXPENDITURE**

Purchase/Lease	Cost
Equipment (Medical, Non-medical, Imaging)	\$575,000
Land/Building Purchase*	
Construction/Renovation**	\$155,000
Other (specify)	
Total Capital Expenditure (TCE)	\$730,000
Lease (Medical, Non-medical, Imaging)***	0
Total Lease Cost (TLC)	0
Total Project Cost (TCE+TLC)	\$730,000

* If the proposal involves a land/building purchase, attach a real estate property appraisal including the amount; the useful life of the building; and a schedule of depreciation.

** If the proposal involves construction/renovations, attach a description of the proposed building work, including the gross square feet; existing and proposed floor plans; commencement date for the construction/ renovation; completion date of the construction/renovation; and commencement of operations date.

*** If the proposal involves a capital or operating equipment lease and/or purchase, attach a vendor quote or invoice; schedule of depreciation; useful life of the equipment; and anticipated residual value at the end of the lease or loan term.

8. Why was there a drop in MRI volume at the Branford facility in FY2013?

The drop in MRI Branford volume at the Branford facility was multi-faceted. Problems existed with the 1T MRI unit that was located in Branford and it was replaced at the end of 2013. There were several significant down time periods throughout 2013 when the unit was out of commission, and patients were either referred to COS MRI unit located in Hamden or other facilities. In December of 2013, the 1T unit was replaced with a refurbished 1.5T GE magnet. This installation took 2 weeks and resulted in additional loss of patient volumes.

9. Why was FY 2015 the sole year used to project the service area given that Branford volume was significantly lower the previous three years?

Between 2014 and 2015, COS merged with four (4) other orthopedic physician group practices. (See CON App., Q. #1, p.16). This merger expanded the total number of physician offices from 8 to 21 for a practice that now has 49 physicians. Patient volume increased from 6,302 scans in FY 2014 to 7,624 scans in FY 2015. The significant expansion of COS in 2014 - 2015 is the primary reason that a second MRI is needed. This volume is not expected to go down in the future because of the large increase of physicians in the COS practice. Therefore, FY2015 is a true reflection of COS patient volume because it reflects the expanded size of COS. It was selected as the base year because it was the most recently completed FY, and the number of scans is actual, not projected.

The four practices that merged with COS are Center for Orthopedics, Shoreline Orthopedics and Sports Medicine, The Orthopedic Group and Orthopedic Health. The merger and resultant increase in the number of COS physicians resulted in a significant increase in the number of MRI scans in 2014, 2015 and projected for 2016. Both of the existing COS scanners (located in Branford and Hamden) experienced increases in the number of scans, all related to the expansion of COS.

10. Please provide articles or patient satisfaction surveys that demonstrate the quality of a mobile MRI?

There are no articles that speak specifically to mobile MRI units. The reality is that there is no difference between a "fixed" MRI vs. a mobile MRI. Both units are 1.5 T in magnet strength. The only difference is that a mobile unit is located within a tractor trailer and is therefore capable of being moved from one location to another. There is no difference in the resolution of the MRI study. The patient experience is essentially the same because the units are identical in capability.

Both existing COS "fixed" MRI scanners have received accreditation from the American College of Radiology (ACR). ACR accreditation will be obtained for the proposed mobile MRI scanner if approved. (CON App., p. 22 and Exhibit H).

11. How would the operation of the proposed mobile MRI conform to the intent of federal law? (Stark)

The proposal meets the in-office ancillary services ("IOAS") exception that is provided to group practices under the Stark law.

The Stark Law, 42 USC §1395nn(a)(1)(b), prohibits a physician from making a referral to a Designated Health Services entity ("DHS entity") for the furnishing of designated health services that would otherwise be covered by Medicare if the physician (or an immediate family member) has a financial relationship with the entity, unless an exception applies 42 USC § 1395nn(a)(1)(b).

The exceptions include the In-Office Ancillary Services (“IOAS”) exception, which allows radiology services such as MRI to be performed within a physician group as long as certain requirements are met. The Applicant, COS, complies with all of the Stark requirements in order to meet the demands of the exception to the general rule.

This is the current law in effect, and there does not appear to be any intent on the part of Congress to eliminate the In-Office Ancillary Services exception. To the contrary, there has been discussion that many of the Stark restrictions are impeding the ability to lower the cost of health care – and as a result, some of the restrictions should be eliminated. In December of 2015, the Senate Committee on Finance and the House Committee on Ways and Means invited a group of subject-matter experts to participate in a round table discussion on issues related to the physician self-referral rule, section 1877 of the Social Security Act, 42 U.S.C. § 1395nn. “Support for Stark law reform has grown in recent years, and following the enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”), Pub. L. No. 114-10 (2015), and other health care reforms, the case for reforming the Stark law has become stronger.” See Senate Finance Committee Majority Staff Report, “Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models” Exhibit R, p. 1.

This “white paper”, published after round table discussions on issues related to the physician self-referral law, stated, “The Stark law has become increasingly unnecessary for, and a significant impediment to, value-based payment models that Congress, CMS, and commercial health insurers have promoted. The risk of overutilization, which drove the passage of the Stark law, is largely or entirely eliminated in alternative payment models.” Exhibit R, p. 2. The case is being made to eliminate the Stark Law completely, not to eliminate the In-Office Ancillary Exception.

While there is still debate about whether to eliminate or restructure the Stark Law in the future, at this time the In-Office Ancillary Service exception is still the law, and the Applicant, COS, conforms to this federal law.

Revised Exhibit List

Exhibit	Description	Pages
A	Map of COS Locations; List of COS Office Addresses; and List of All COS Physicians.	59 - 68
B	Graphs of Increased MRI Scanning in Hamden and Branford FY 2013 – 2016.	69 - 72
C	DPH License for Outpatient Surgery Center in Branford.	73 - 74
D	List of Key Professional, Administrative, Clinical and Direct Service Personnel and Curriculum Vitae	75 - 91
E	Scholarly Articles	92 – 122
F	Letters of Support	123 - 130
G	COS Standard of Practice Guidelines	131 – 171
H	American College of Radiology Accreditation for Existing MRI Scanners	172 – 174
I	COS Charity Care Policy	175 – 176
J	Target Populations: Patient Zip Codes	177 – 193
K	FY2015MRI Scans in the Essex Area for COS Patients	194 – 196
L	FY2015MRI Scans in the Orange Area for COS Patients	197 – 198
M	Capital Expenditures for Mobile MRI	199 – 203
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O	COS Financial Statements; Balance Sheets and Related Income Statements for FY 2014 and 2015	209 – 213
P	Financial Worksheet	214 – 215
Q	Assumptions Used in Financial Worksheet	216 – 218
R	Senate Finance Committee Majority Staff Report, “Why Stark, Why Now?”	228 - 248

EXHIBIT R

Why Stark, Why Now?

Suggestions to Improve the Stark Law to Encourage
Innovative Payment Models



A Senate Finance Committee Majority Staff Report

Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models

Senate Committee on Finance, Majority Staff
Chairman Orrin Hatch (R-Utah)

I. INTRODUCTION

On December 10, 2015, the Senate Committee on Finance and the House Committee on Ways and Means invited a group of subject-matter experts to participate in a round table discussion on issues related to the physician self-referral law, section 1877 of the Social Security Act, 42 U.S.C. § 1395nn, also known as the Stark law.

The Stark law prohibits a physician from referring Medicare patients for “designated health services” (DHS) to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies.¹ Financial relationships include both ownership and investment interests, as well as compensation arrangements. In addition, the law prohibits an entity from billing the Medicare program for services provided pursuant to an impermissible, or tainted, referral.

Support for Stark law reform has grown in recent years, and, following the enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Pub. L. No. 114-10 (2015), and other health care reforms, the case for reforming the Stark law has become stronger. The strict liability regime, huge penalties, and the breadth, complexity, and ambiguities of the Stark law and its regulations have created what is often referred to as a minefield for the health care industry. With this backdrop, attempts by Congress, the Centers for Medicare & Medicaid Services (CMS), and the private sector to encourage value-based payment models have not effected change as quickly as some had hoped. While many providers would like to move toward alternative payment models, most are reluctant to do so because they must contend with the tension between the Stark law and alternative payment models and the possibility of devastating penalties if they guess wrong.

The round table participants discussed whether changes to the law were necessary to implement MACRA and, if so, what options would work best in a system that includes both the fee-for-service (FFS) payment model and alternative payment models. After the meeting, the Committees invited the round table participants and others to share their views on the Stark law.²

The round table participants and the groups that submitted comments for the Committees’ review included Stark law experts, academics, attorneys in private practice who work with

¹ Section 1903 of the Social Security Act, 42 U.S.C. § 1396b, prohibits payment of the federal share of Medicaid to states for services paid under Medicaid that would have constituted a prohibited referral under Medicare.

² In 2009, the Public Interest Committee of the American Health Lawyers Association (AHLA) sponsored a “Convener on Stark law” (Convener Session) held on April 24 and June 30, 2009, in Washington, D.C. A white paper was published entitled, [A Public Policy Discussion: Taking the Measure of the Stark Law](#), which summarizes the discussion and proposals for changing the

hospitals and/or physicians, attorneys in the private sector who previously served in government regulatory and enforcement agencies, hospital systems, electronic health record providers, as well as associations representing hospitals, physicians, medical device manufacturers, accountable care organizations, and several types of ancillary service providers.

II. EXECUTIVE SUMMARY

Congress enacted the Stark law to limit the influence of financial relationships on physician referrals. If a physician (or an immediate family member) has a financial relationship with an entity, then the physician may not make a referral to the entity for the furnishing of DHS under Medicare and, to some extent, Medicaid, unless an exception applies. 42 U.S.C. § 1395nn; 42 U.S.C. § 1396b. A “financial relationship” is defined as any direct or indirect (1) ownership or investment interest or (2) compensation arrangement by or between a physician (or an immediate family member of the physician) in the entity providing the DHS. An entity may not bill for DHS provided as the result of a tainted referral.

Congress intended the Stark law to provide a bright line test to curb physician self-referral. But despite CMS’s efforts to provide clear rules and interpretations to address the strict liability regime, the Stark law’s breadth, complexity, and impenetrability have created a minefield for the health care industry. As Judge James A. Wynn of the United States Court of Appeals for the Fourth Circuit noted last year, “even for well-intentioned health care providers, the Stark law has become a booby trap rigged with strict liability and potentially ruinous exposure – especially when coupled with the False Claims Act.” [United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.](#), No. 13-2219, 2015 U.S. App. LEXIS 11460 at *56, *69 (4th Cir. July 2, 2015) (Wynn, J., concurring).

The Stark law has become increasingly unnecessary for, and a significant impediment to, value-based payment models that Congress, CMS, and commercial health insurers have promoted. The risk of overutilization, which drove the passage of the Stark law, is largely or entirely eliminated in alternative payment models. When physicians earn profit margins not by the volume of services but by the efficiency of services and treatment outcomes, their economic self-interest aligns with the interest to eliminate unnecessary services. Before Congress passed health care reform, the health care industry recognized that the Stark law would be an obstacle to hospitals’ and other providers’ efforts to align incentives with physicians for certain alternative payment models, including pay-for-performance, gainsharing, bundled payment or outcomes measures. During the American Health Lawyers Association’s (AHLA) 2009 Stark discussion, many participants noted that alternative payment programs inevitably link physician payments to

law itself or its administration or enforcement. Although the topics covered do not overlap precisely, our December 2015 round table was an effort to look at what changes had taken place since 2009, given the passage of the Affordable Care Act in 2010 and MACRA in 2015. The views shared by the round table participants and subsequent commenters reflect the changing legal landscape between 2009 and the present, but they also echo many of the underlying issues discussed in the 2009 AHLA session.

the volume or value of physician referrals³ – a payment formula that generally will not pass muster under the compensation arrangement exceptions to the Stark law.⁴

Congress also recognized that alternative payment models would be difficult or impossible to establish in the current FFS enforcement environment. As a result, the Affordable Care Act (ACA) included an authorization for the Health and Human Services (HHS) Secretary to issue regulatory waivers from the Stark law and other fraud and abuse laws for innovative payment and service delivery models.⁵ Under that authority, the Secretary has issued waivers from fraud and abuse laws for participants in the Medicare Shared Savings Programs (MSSP), the Bundled Payments for Care Improvement Initiative (BPCI), the Comprehensive Care for Joint Replacement (CJR), and other Accountable Care Organization (ACO) programs.

MACRA's modification of the Civil Monetary Penalties (CMP) law, 42 U.S.C. § 1320a-7a, (specifying that the gainsharing prohibition applies only to inducements made to reduce or limit medically necessary services to beneficiaries) has removed some barriers to gainsharing and pay-for-performance programs. Nevertheless, as the waivers for CMS demonstrations illustrate, the Stark law continues to pose significant risks for implementation of such programs. Importantly, Medicare waivers do not protect all alternative payment models under MACRA or with commercial payers, undercutting hospitals' ability to provide uniform and consistent incentives for physicians across all patient populations.

The Committees invited the round table participants to consider an array of known issues, including the current Stark law environment, health care reform implementation, costs associated with compliance and disclosures, possible fixes under both FFS and alternative payment models, and CMS's limited authority to create exceptions and to issue advisory opinions. Round table participants were then asked to specifically focus on (1) changes to the Stark law to implement health care reform, specifically MACRA, and (2) the distinction between technical and substantive violations.

Although the comments that we received were wide-ranging, there were many recurring themes. To implement health care reform, many comments focused on potential new waivers or exceptions, expansion of existing waivers or exceptions, broadening CMS's regulatory authority, repealing the compensation arrangement prohibition, or repealing the law in its entirety. Comments also concentrated on other important non-MACRA issues, including changes to standard Stark law definitions, like fair market value, the volume and value of referrals, and commercial reasonableness. In distinguishing technical and substantive violations, comments centered on documentation requirements and harm to beneficiaries or federal health care programs.

³ Reducing unnecessary FFS procedures or services reduces costs but increases profit (*i.e.*, value).

⁴ AHLA, [A Public Policy Discussion: Taking the Measure of the Stark law](#), at 9 (2009) (hereinafter, [AHLA 2009 White Paper](#)).

⁵ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3022, (2010).

Some commenters submitted other suggestions for improving the law, including changes or clarifications to in-office ancillary services exception, the physician-owned hospital exception, documentation requirements, and others. This white paper focuses on potential changes to the Stark law to remove hurdles to implementing health care reform and on how to distinguish technical and substantive violations. The other issues that are not addressed in detail in this white paper may be considered by the Committee at a future point in time.

III. STARK LAW BACKGROUND

Under an FFS payment model, physicians have a financial incentive to provide more services. When a physician has a financial interest in an entity to which he or she refers patients, the incentive extends to ordering tests, procedures, or referring patients to that entity. The issue received attention in the 1980s, and, by 1989, the HHS Office of Inspector General found that physician self-referral related to laboratory tests was associated with a marked increase in utilization.⁶

That year, Congress passed the Ethics in Patient Referrals Act of 1989 (Stark I) prohibiting a physician (or an immediate family member) who had a financial relationship with a clinical laboratory services entity from referring Medicare beneficiaries to the entity, unless an exception applied. Stark I also prohibited the lab from billing for any services furnished pursuant to a tainted referral. To prevent the law from being circumvented by contractual structures that did not involve equity but gave physicians the benefits of ownership, Congress also prohibited circumventions schemes and compensation arrangements. Stark I became effective January 1, 1992. Congress soon expanded the clinical laboratory prohibition to ten “designated health services” in the Omnibus Budget Reconciliation Act of 1993 (Stark II), which became effective January 1, 1995. Stark I and Stark II each included exceptions to the general prohibition.

CMS has published a series of regulations implementing the Stark law, beginning in 1992.⁷ The final rules, listed below, are codified at 42 C.F.R. § 411.350–411.389.⁸

- Stark I regulations, August 14, 1995.
- Stark II Phase I regulations, January 4, 2001 (interim final rule).
- Stark II Phase II regulations, March 26, 2004 (interim final rule).
- Stark II Phase III regulations, September 5, 2007.
- Stark II Phase IV, Inpatient Prospective Payment System (IPPS) regulations, August 19, 2008.
- Stark II Phase V, IPPS regulations, October 30, 2015.

⁶ OIG-Office of Analysis and Inspections, Report to Congress, [Financial Arrangements Between Physicians and Health Care Businesses](#), 3 (May 1989).

⁷ AHLA’s [2009 White Paper](#) includes a chart with a helpful description of the regulatory changes from 1992 through 2009, at pages 4-5.

⁸ The CMS website has a list detailing the Stark law’s [significant regulatory history](#).

Several commenters stated that the Stark law is not a “fraud” statute, but a regulation of payment. There is no requirement of an intent to violate the statute and compliance is a straightforward condition of payment. These commenters noted that Congress intended to provide a bright line rule, which would encourage hospitals and other providers to self-police their arrangements with physicians.

Even with regulatory exceptions and guidance, the result has been an extremely broad prohibition on physician referrals. If a physician has a financial relationship with an entity, any referrals by the physician to that entity are prohibited unless the financial relationship fits within one or more exceptions.⁹ But the round table participants characterized the exceptions as illusory because the three key standards in most exceptions—fair market value, “takes into account” volume or value of referrals, and commercially reasonable—are factual, which means parties must prove that their arrangement fits into the exception at trial. Moreover, the participants and commenters noted that the three standards are ambiguous, and thus lead to unpredictable outcomes. The unpredictability is especially frustrating given the enormous penalties under the Stark law, which can be much higher than penalties for fraudulent activity.¹⁰

Commenters also noted the high cost and difficulty of complying with the Stark law. Even tracking non-monetary compensation issues can cause headaches for hospitals and physicians. For instance, if a physician agrees to join an ACO, it makes sense to provide access to the same electronic health record system used by the rest of the network. While the current MSSP waivers address this concern, if the physician leaves the ACO, or when the waivers expire, the physician may face Stark liability, which is just one additional hurdle to physicians joining ACOs and other integrated health care entities.

Some participants noted the law’s inflexibility, as it prohibits any financial arrangement with a physician that does not fit within an exception. This inflexibility is underscored as providers attempt to implement alternative payment models like ACOs, pay-for-performance, shared savings, and bundled payments, which do not always fit into existing exceptions. Participants and commenters generally agreed that the Stark law does not have a place in the pay-for-value world because it was created to address overutilization in an FFS environment. Many participants and commenters believe that the law is disruptive to the development and implementation of value-based models.

⁹ The requirement that the financial relationship fit within an exception is different than the option to fit a relationship within a safe harbor to the Anti-Kickback Statute (AKS). Under the AKS, financial relationships that do not fit squarely within a safe harbor do not necessarily violate the AKS.

¹⁰ If a hospital has a non-compliant financial arrangement with a physician, all Medicare payments for all inpatient or outpatient services from that physician are “overpayments” and must be returned, regardless of the amount of the “tainted” transaction or nature of the payment. In contrast, even the new authority in the ACA expanding the false claims liability for violations of the AKS is limited to claims “resulting from” the kickback.

Although many areas for improvement were discussed, especially those to usher in health care reform, round table participants and commenters also recognized that the Stark law has been effective in restricting physician ownership and investment in entities such as free-standing imaging centers and other providers of ancillary services. The law has also encouraged the industry to focus on compliance because of the need to closely scrutinize physician relationships, but several commenters noted that in practice the burden of compliance falls upon hospitals. Round table participants praised the establishment of the Self-Referral Disclosure Protocol, which enables providers to disclose Stark violations and permits CMS to compromise repayment amounts. Some participants noted that the settlements under the Protocol have been fair and reasonable. But several participants believe that the process is too time consuming and does not provide certainty to disclosing parties. Some commenters point to exceptionally high settlements for disclosures of technical violations based on documentation issues alone.

IV. STARK LAW IN CONTEXT

Round table participants and commenters discussed the Stark law in the context of other enforcement authorities and reimbursement rules that may also address physician self-referral practices.

Anti-Kickback Statute. Many commenters noted the imperfect and often confusing overlap between the Anti-kickback statute (AKS), 42 U.S.C. § 1320a-7b, and the Stark law.¹¹ Relationships that are permissible under the Stark law may violate the AKS, which some commenters said means the Stark law occasionally undermines the enforcement of the AKS. When Congress passed the Stark law, there was no civil liability for anti-kickback violations under the CMP law, and it was unclear whether the government could use an anti-kickback violation as a predicate for a False Claims Act (FCA) case.

With the expansion of the scope and application of the AKS over the years, however, many participants and commenters argue that the Stark law is no longer needed. The AKS can now be enforced in the civil context through the FCA and the CMP law. Not all participants agreed that the Stark law was no longer needed, in part because the FFS payment model would still be used to some extent for years to come.

Compounding the complicated overlap between these two statutes, is the disproportion in penalty levels. Penalties are smaller for AKS violations, which require knowing and willful intent, meaning the underlying conduct is arguably much more egregious.

False Claims Act. The FCA has become the primary enforcement mechanism of the Stark law. 31 U.S.C. § 3729–3733. While the Stark law prohibits physician referrals to an entity based on non-compliant financial relationships, from an FCA perspective, the focus is on the prohibition on billing for services furnished pursuant to a tainted referral. FCA exposure is created if the claims were submitted with the requisite intent (reckless disregard or deliberate

¹¹ While this may be an area that would benefit from further examination by Congress, the AKS is outside the Finance Committee’s jurisdiction, and while we may refer to comments that mention the AKS, we are unable to address those concerns at this time.

ignorance of their truth or falsity). The Fraud Enforcement and Recovery Act of 2009 (FERA) expanded the potential for FCA exposure by revising the definition of a claim to include the knowing and improper retention of an overpayment.¹² 31 U.S.C. § 3729(a)(1)(G). In 2010, the ACA added the “60-day rule” requiring providers to “report and return” a Medicare or Medicaid overpayment within 60 days “after the date on which the overpayment was identified.” 42 U.S.C. § 1320a-7k(d)(1)–(3). Thus, under the FCA’s reverse false claims provision, an entity that submits a claim with no knowledge that it may be prohibited by the Stark law may face FCA exposure if (1) the entity later discovers the Stark violation and (2) fails to report and return any reimbursement associated with the tainted claim within the 60-day period.¹³

Some commenters expressed concerns with recent FCA litigation, noting that certain aspects of the Stark law have led to a number of recent FCA settlements that threaten the development of integrated delivery systems. The commenters pointed to several recent FCA settlements based on a *qui tam* theory that an accounting loss for hospital-owned physician practices is *ipso facto* evidence that the employed physicians are paid more than fair market value and that the arrangement is not commercially reasonable. The commenters acknowledge that the complaints for some of the recent settlements may involve extreme facts but are nonetheless concerning as potential examples of bad facts making bad law.

Reimbursement. Some round table participants noted that reforming reimbursement rules may address the Stark law’s underlying concern of overutilization. Some suggestions included decreasing reimbursement for ancillary services provided through a physician’s group practice, bundling the payment for physician office visits and ancillary services, and adopting bundled payment plans that promote shared risk among providers involved in an episode of care.¹⁴ Although we did not receive comments in direct opposition to these suggestions, we received numerous comments both in favor of and against any changes to the in-office ancillary services exception which could serve as an alternative to payment changes for such services.

V. IMPLEMENTING MACRA AND OTHER ALTERNATIVE PAYMENT MODELS

As noted above, the Committees invited round table participants and others to share their perspectives on what changes to the Stark law might be necessary to implement health care reforms promoting alternative payment models, such as MACRA. Participants were asked to

¹² Prior to FERA, liability for retention of an overpayment required an affirmative step to evade repayment through a false record or statement and only if it could be established that repayment was an “obligation.” This provision became known as a reverse false claim.

¹³ In rejecting two motions to dismiss, the District Court for the Southern District of New York recently addressed what it means to “identify” an overpayment and start the clock for the 60-day rule under the FCA. *U.S. ex rel. Kane v. Healthfirst, Inc., et al.*, No. 11 CIV 2325, 2015 U.S. Dist. LEXIS 101778 (S.D.N.Y. Aug. 3, 2015).

¹⁴ For additional reimbursement suggestions shared during AHLA’s Convener Session, see, [AHLA 2009 White Paper](#), at 12.

include in their suggestions options that would work in a payment environment that includes both FFS and alternative payment models.

The comments generally focused on potential new waivers or exceptions, expansions of existing waivers or exceptions, changes to standard Stark law definitions, broadening the Secretary's authority, or repealing the law or the compensation arrangement prohibition. The relevant comments are summarized by category below.

Repeal. Many commenters suggested that the Stark law has outlived its utility. These commenters argue that the AKS in its current form can address the conduct that the Stark law seeks to curtail. However, some commenters noted that the Stark law addresses conduct that may not fall under the AKS. Additionally, while the FFS payment model is being phased out, it will continue in some form for many years. With this in mind, some commenters advocating repeal recommended that the Stark law be sunset once Medicare had transitioned to alternative payments to a meaningful extent.

Repeal Compensation Arrangement Prohibitions. A larger group of commenters believed that repealing the compensation arrangement requirements would address many of the concerns not only with implementing health care reform but with the Stark law's most difficult provisions. They recommend limiting the Stark law to ownership and investment interests, which they believe was Congress's original intent. However, as some commenters noted, prohibitions on compensation arrangements have been in the law from the beginning and were included to avoid schemes to circumvent the law with creative arrangements that would give physicians the benefits, and dangers, of ownership but that did not involve equity.¹⁵ Other commenters argued that the compensation arrangement prohibitions are no longer necessary because the AKS can now be enforced in a civil context through both the FCA and the CMP law.

New Risk Revenue Waiver/Exception. To lessen the burden of health care entities making the transition from FFS to alternative payment models, two commenters recommended creating a waiver from the Stark law once a health care entity's risk revenue reaches a certain majority percentage of its total revenue. Health care entities receiving such a waiver would be required to meet certain criteria, for example, having the governing board of the ACO entity approve applicable financial relationships through a process that validated Triple Aim¹⁶ principles and shows no motivation to increase utilization. Noting that some health care entities would never reach this level of risk based revenue, one of the commenters acknowledged that entities that did not reach such a level of risk engagement would still be required to meet a Stark

¹⁵ [AHLA 2009 White Paper](#), at 12.

¹⁶ See Donald M. Berwick, et al., [The Triple Aim: Care, Health, And Cost](#), Health Affairs, May/June; 2008, 27(3) at 759-769. "The Triple Aim is a framework developed by the Institute for Healthcare Improvement that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimensions, which we call the "Triple Aim": Improving the patient experience of care (including quality and satisfaction); Improving the health of populations; and Reducing the per capita cost of health care." IHI website, [Triple Aim Initiative](#).

exception for certain arrangements. The other commenter framed the exception in terms of health care systems that derive no less than 50 percent of their health care revenue from alternative payment methodologies, and recommended that such systems receive a broad waiver from the Stark law similar to those now in effect for ACOs.

The commenters believe that enforcement agencies could use the AKS and the gainsharing CMP to address problematic arrangements. This idea accommodates the incremental transition to value-based payment models. However, some round table participants questioned how health care entities could reach a threshold percentage without being at risk, arguing that this type of fix would simply shorten the period of exposure for a subset of providers.

Create New or Expand Currently Restricted Waivers. Most commenters suggested extending the waivers that are currently highly limited to CMS-run programs to all payers. Many commenters believed that expanding the waivers for the MSSP to qualifying alternative payment model participants would be the best solution.¹⁷ Some urged that the same protections be provided to physicians operating in alternative payment models that were provided through ACOs eligible for MSSP, including the pre-participation period. Those commenters believe this would recognize the variety of alternative payment models that use different mechanisms and structures to encourage efficient care. One commenter stated that, ideally, Congress would make the current Center for Medicare & Medicaid Innovation (CMMI) waivers permanent and available to all new adopters of similar models in the future, as well as permanent programs established under the CMMI's authority.

Commenters agreed not only that Congress should create waivers to address the problem but also that Congress should give HHS broader authority to create regulatory waivers. While commenters generally agreed that some new waivers could be created through existing but limited CMS rulemaking authority, most agreed that Congress should give CMS express authority to create broader waivers than currently authorized by law.¹⁸

Some commenters argued for consistency in fraud and abuse laws' applicability to ACO programs for all government-supported innovative payment models. One suggestion to accomplish such consistency was the creation of a new Stark law exception at 42 U.S.C. § 1395nn(b) that would apply to MIPS, physician-focused payment models, and payments associated with alternative payment models. Another suggestion was to create a waiver that would apply to MIPS, alternative payment models, and ACOs, modeled on current Stark exceptions for Medicare prepaid plan enrollees. These type of waivers could address issues in an environment that includes both FFS (MIPS) and alternative payment models.

¹⁷ CMS and OIG, HHS, [Medicare Program; Final Waivers in Connection With the Shared Savings Program, 80 Fed. Reg. 66,726](#) (Oct. 29, 2015) (codified at 42 C.F.R. Chs. IV and V).

¹⁸ Recommendations to expand the Secretary's authority to create waivers and exceptions are discussed below.

Create New Exceptions. Many commenters suggested the creation of a new exception to enable financial arrangements that involve risk-sharing and gainsharing in alternative payment models when appropriate safeguards are in place. Some recommended that such an exception (the “APM Exception”) apply to all MACRA alternative payment model financial arrangements and expressly allow for compensation arrangements that take into account the volume or value of referrals, and that it not impose a fair market value requirement. At least one commenter recommended a new exception for quality-based payments to physicians, provided that such payments are not tied to the volume or value of referrals.

Other commenters stated that a new exception should be available for financial relationships designed to foster collaboration in the delivery of health care and incentivize and reward efficiencies and improvements in care (referring to integrated delivery systems, accountable care, team-based care, or value-based payment arrangements). Some commenters, concerned that an exception may focus on institutional providers, expressed the need for an exception that took into account the breadth and scope of providers and entities necessary for truly integrated health care. Other commenters emphasized that the new exception should be available for truly clinically integrated arrangements designed to achieve the efficiencies and care improvement goals of new payment models. Commenters also noted the need to protect shared savings and incentive programs, as well as any arrangement start-up or support contribution, when certain conditions are met.

One commenter suggested an approach to accommodate alternative payment models, either under MACRA or more broadly, that would involve adding an additional statutory exception for alternative payment models that promote and advance accountability for quality, cost/risk, care coordination, patient experience, and outcomes. To qualify for the exception, which could be added to the compensation arrangement exceptions at 42 U.S.C. § 1395nn(e), arrangements would need to meet conditions that are already used to qualify ACOs and other risk-sharing arrangements under the Stark law and AKS. These safeguards include written agreements, transparency, and provider accountability, as well as prohibitions on double billing or shifting costs to federal health care payers.

Special Compensation Rule. The majority of comments touched on potential changes to how the Stark law treats compensation arrangements. As an alternative to an integrated delivery system waiver, some commenters recommended changing the fair market value requirement or the fair market value definition to accommodate alternative payment models. One commenter suggested a special compensation rule related to MACRA alternative payment model financial arrangements that would automatically deem such arrangements to (1) not take into account the volume or value of referrals, or other business generated between the parties, and (2) constitute fair market value, provided all MACRA alternative payment model programmatic requirements were otherwise met.

Modify Existing Exceptions. Commenters also suggested modifying existing statutory or regulatory exceptions to the Stark law to promote integrated care and aligned incentives.

Most Stark law exceptions protect a “financial relationship” and except the relationship from triggering the prohibition on DHS referrals. Other exceptions, like the prepaid plan exception at 42 U.S.C. § 1395nn(b)(3), only protect the services that would otherwise be

prohibited DHS referrals. The prepaid plan exception, for example, only protects referrals of services to the prepaid plan but still prohibits FFS referrals to the same party. Several commenters recommended Congress broaden the statutory prepaid plan exception so that the prohibition on referrals for DHS would not apply to services rendered by an entity that has a contract with CMS or its agent that contemplates the use of alternative payment models. Alternatively, the exception could be framed so that it protects DHS furnished to a Medicare beneficiary who is assigned to an MSSP, Pioneer, or Next Generation ACO, or any other ACO model established by CMS or tested under CMMI. Either scenario should protect services that would otherwise be prohibited DHS referrals; FFS referrals to the same party would still be prohibited. These commenters argue that this would provide more certainty for the regulated community than an extension of the regulatory waiver approach for ACO arrangements.

Several commenters recommended Congress expand the risk-sharing exception at 42 C.F.R. § 411.357(n) to apply to Medicare and Medicaid FFS programs. Other commenters would expand the exception to incentive payment arrangements between a DHS entity and a physician participating in a qualified alternative payment model (others framed this as applying to compensation arrangements involving integrated care organizations). Some commenters recommended that a new exception be created based on the risk-sharing exception that would apply to MSSP, Pioneer, Next Generation ACO, or other CMS or CMMI ACO models, as long as the arrangement is reasonably related to one of the purposes of the respective program. The exception would explicitly cover payment arrangements that are downstream of bundled payments, shared savings, and other alternative payment programs implemented by governmental or private payers. Commenters advocated for consistency between the Stark law and the CMP law, stating that the Stark law should not prohibit any arrangement presently permitted under the CMP law, as amended by MACRA, specifically the modifications to the gainsharing prohibition. They also recommended a clarification that the volume and value standard under the Stark law is not implicated when a physician is incentivized to follow a standard hospital quality measure (*e.g.*, a care protocol) that includes ordering an item or service for a patient that will not result in any additional reimbursement to the hospital.

One commenter recommended Congress codify the existing exception applicable to services furnished by an organization (or its contractors or subcontractors) to enrollees set forth at 42 C.F.R. § 411.355(c), and modify it to incorporate alternative payment models, including those involving integrated care organizations, as being eligible for protection.¹⁹

Another commenter noted that although the current Stark rules do not pose major obstacles for parties to enter into bundled payment or gainsharing arrangements, some legislative changes or clarifications to the Stark law could provide much needed comfort for parties who are uncertain how to proceed or fear inappropriate enforcement efforts.

One area the commenter identified for clarification is the definition of an indirect compensation arrangement, which, along with the exception for indirect compensation

¹⁹ For purposes of consistency, the commenter recommended that the definitions of health plan and enrollees under 42 C.F.R. § 1001.952(1) be modified to contemplate ownership and compensation relationships arising out of alternative payment models.

arrangements, is one of the most complex and frustrating areas of Stark regulation. The definition includes three components. One of those components is based on the referring physician's receipt of aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS. *See* 42 C.F.R. § 411.354(c)(2)(ii). The commenter recommends that Congress clarify that where the physician's compensation from an entity with which he or she has a direct compensation arrangement does not necessarily rise as a direct result of more referrals or higher paying referrals, the aggregate compensation test is not met.

Additionally, the commenter notes that although arrangements where physicians are paid a percentage of savings are common, CMS has never expressly recognized that a percentage of savings can be fair market value and commercially reasonable. To resolve uncertainty and to promote non-abusive shared savings arrangements, the commenter recommended that Congress adopt CMS's deeming provision for per-click compensation arrangements, 42 C.F.R. § 411.354(d)(2), and extend it to percentage compensation arrangements. The commenter also recommended that Congress amend the Stark law to state that an arrangement under which a physician receives a percentage of saving realized by a provider can satisfy the fair market value and commercial reasonableness requirements of an applicable exception. Alternatively, Congress could provide that an arrangement under which a physician would receive a percentage of savings realized by the hospital or other provider or supplier will be presumed (or deemed) to satisfy the fair market value and commercial reasonableness requirements of an applicable exception if the parties relied in good faith on an opinion from a nationally recognized appraisal firm. To prevent opinion shopping, the statute must provide that all opinions (draft or otherwise) of fair market value and commercial reasonableness would be taken into account when determining whether the parties relied in good faith on a favorable opinion. One commenter suggested that such a change should include some standard to govern the amount that can be shared with physicians, such as a cap or threshold.

Expand the Secretary's Authority: Waivers, Exceptions, and Advisory Opinions. Some commenters noted that the Stark law and regulations are payment regulations that providers must comply with to receive payment. An effective regulatory regime requires that the regulated community be able to obtain timely and clear guidance. Commenters offered a number of suggestions in this regard.

Commenters generally agreed that Congress should expand the Secretary's authority to create waivers, exceptions, and advisory opinions. Although some commenters suggested that the authority be limited to expanding waivers for participants in MSSP and other CMMI models, most recommended that the Secretary be given express waiver authority that would apply to innovative payment models under MACRA and other health care reform laws.

The Stark law permits the Secretary to create regulatory exceptions that the Secretary determines do "not pose a risk of program or patient abuse." 42 U.S.C. § 1395nn(b)(4). CMS has taken a cautious approach in issuing Stark exceptions.²⁰ Commenters believe that many of

²⁰ Although CMS recently provided additional guidance on the Stark law, [Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70885](#), 71300-71341 (Nov. 16, 2015), at least one commenter

the existing exceptions are too narrow or complicated to be useful but that more practical exceptions could be issued if the Secretary were given authority to create exceptions where an arrangement does not pose an undue or significant risk of program or patient abuse. Commenters also noted that HHS has greater authority and flexibility to create safe harbors to the AKS, a criminal statute, than it has to create exceptions to the Stark law, a regulation of Medicare payment.

Several commenters also urged Congress to strengthen the Secretary's authority to issue Stark advisory opinions and promote timely agency guidance. One commenter noted that if an exception for innovation arrangements were adopted, it could permit the submission of a request through the CMS advisory opinion process, which would provide added comfort to both CMS and the industry. The commenter noted that Congress could direct CMS to modify its current regulations to accommodate the review process and set forth other requirements CMS considers necessary to organize, facilitate, and fund the analysis and the timely issuance of advisory opinions dealing with innovation arrangements that promote the Triple Aim. This commenter noted that such advisory opinions should not be required, but that they should be available to provide added comfort to the industry in a time of innovation and change.

The participants and commenters agreed that the creation of the Self-Referral Disclosure Protocol (SRDP) and the expansion of the Secretary's authority to compromise Stark repayment obligations were positive developments in Stark law enforcement. Nevertheless, some said the process was too lengthy and left providers in limbo while they waited for a disposition. Many commenters argued Congress should give CMS more discretion to settle Stark law violations, such as providing CMS with the explicit authority to impose CMPs in lieu of compromising repayments based on the total repayment amount.²¹ One commenter suggested Congress give CMS discretion to determine whether to prohibit billing for violations, which could have far-reaching implications, including taking Stark law violations out of the realm of FCA litigation.

Some commenters were not enthusiastic about creating additional waivers or exceptions to the Stark law because they believe that regulatory environment is already overly complex. These commenters also believed it would not be effective to simply strengthen the Secretary's advisory opinion authority to promote timely agency guidance because, based on 25 years' worth of rule-making, they believe Congress should revise the law entirely. In their view, advisory opinions only help at the margins, and, in almost all cases, very slowly.

VI. DEFINING TECHNICAL VIOLATIONS

Commenters generally agreed that "technical" violations should be subject to a separate set of sanctions that would not give rise to either FCA exposure or potentially ruinous repayment

believed that the agency could be more hesitant to issue exclusions after the recent decision in *Council for Urological Interests v. Burwell*, 790 F.3d 212 (D.C. Cir. 2015). This concern underscores the importance of consideration of an explicit grant of authority to the Secretary.

²¹ Recommendations concerning a revised penalty structure are discussed below.

liability.²² Several commenters noted that Congress recognized the disparity between technical and substantive violations when it created the SRDP and authorized the Secretary to reduce amounts owed. In distinguishing technical and substantive violations, comments focused on documentation requirements, adherence to fair market value, the volume or value of referrals, or harm to beneficiaries or federal health care programs. But some commenters questioned whether drawing such a distinction would be helpful because it would be difficult to determine penalty provisions and enforcement priorities in an already hyper-technical environment. Their solution to the complexity would be to eliminate the compensation arrangements prohibition. As for penalties for technical violations, all commenters recommended that CMPs be assessed in lieu of penalties or that no penalty be assessed. Some commenters recommended further reducing the CMP if a party self-disclosed a violation within 60 days of discovery.

Documentation Requirements. Commenters generally agreed that technical violations were those involving the form, not substance, of an arrangement. Commenters and round table participants pointed to Representative Charles Boustany’s proposed legislation, the Stark Administrative Simplification Act of 2015, as a move in the right direction, specifically in terms of its definition of technical violations.²³ The proposed legislation defines “technical noncompliance” as arrangements that violate the law’s prohibition of self-referral “only because (i) the arrangement is not set forth in writing; (ii) the arrangement is not signed by 1 or more parties to the arrangement; or (iii) a prior arrangement expired and services continued without the execution of an amendment to such arrangement or a new arrangement.”²⁴

Several commenters added that technical violations are those that pose a low risk of affecting the Medicare fisc and are unlikely to result in increased use of medically unnecessary services.

Arrangements That Do Not Incentivize Referrals or Unduly Influence Health Care Decision-Making. In describing technical violations, some commenters included along with documentation requirements violations that are irrelevant to whether an arrangement incentivizes referrals. Outside the context of ownership, they only consider “substantive” violations of the Stark law to be compensation structures that induce or reward referrals (*i.e.*, the physician is paid for referrals). Some of these commenters recommended eliminating any technical violations that do not harm patients or Medicare and authorizing the Secretary to impose a CMP for each arrangement to reduce the impact of technical violations. One commenter suggested that a financial arrangement that a reasonable person would conclude creates a significant incentive to a physician to refer to a particular entity is substantive.

Fair Market Value. Some commenters suggested dividing violations into two categories: (1) those where compensation is in excess of fair market value (and perhaps commercial reasonableness) and/or is determined in a manner that takes into account the volume

²² [AHLA 2009 White Paper](#), at 16.

²³ [Stark Administrative Simplification Act of 2015](#), H.R. 776, 114 Cong. (2015).

²⁴ [Stark Administrative Simplification Act of 2015](#), H.R. 776, 114 Cong. (2015).

or value of referrals; and (2) those where compensation is not. However, commenters recognized that the division is not clear cut in practice due to the technical nature of the rules on fair market value and volume or value of referrals. Many commenters and participants agreed that any meaningful change to the Stark law must address volume and value, and, to a lesser extent, fair market value.²⁵ One suggestion was to define technical violations to include any violation that does not involve fair market value (and perhaps commercial reasonableness) or the volume or value prohibition; and that, depending on the facts and circumstances, technical violations may include violations that involve fair market value, commercial reasonableness, or the volume or value prohibition.

Compensation Arrangements That Do Not Violate the AKS. Several commenters recommended defining technical violations as compensation arrangements that do not otherwise violate the AKS. In other words, as suggested above, prohibited ownership violations would be substantive noncompliance, and problematic compensation arrangements would be enforced through the AKS or the CMP law. One commenter suggested that any arrangements that do not confer a financial benefit to the referring physician should not be considered substantive and that technical violations should not carry Stark penalties.

Create Bright Line Requirements For Substantive Noncompliance. One commenter suggested first creating bright line requirements to improve clarity and then considering all noncompliance with those bright line requirements to be substantive. The commenter recommended that Congress direct CMS to specify, on a regular basis (*e.g.*, through Medicare Physician Fee Schedule rule making), compensation practices that are not permitted based on the agency’s experience. Only noncompliance with such specifically non-permitted compensation practices should be viewed as substantive noncompliance. As discussed below, concerns have been raised about Congress’s or CMS’s ability to create a list that would effectively cover all financial arrangements that may involve self-referral concerns.

Clarify Compensation Arrangement Terms. Several commenters recommended clarification of the three key terms in the compensation arrangement exceptions: fair market value (FMV), “takes into account” the “volume or value” of referrals, and commercially reasonable. The comments we heard echoed those raised during the AHLA discussion, including concerns about the difficulty of establishing and documenting FMV.²⁶

Some commenters recommended allowing physician compensation for providing high-quality and efficient care without violating the Stark law’s FMV standard, even if the compensation is related to the volume or value of the referrals. These commenters argue that the statutory definition of FMV simply reflects the clear rule that arrangements must reflect arm’s length bargaining and that the “volume or value” standard was a regulatory addition created by CMS. Another commenter also rejected CMS’ definition of FMV and recommended that Congress clarify that intent is not material in the strict liability law, and bar CMS from defining

²⁵ We received many comments recommending changes to terms associated with compensation arrangement exceptions. They are discussed in Section VI, below.

²⁶ See [AHLA 2009 White Paper](#), at 11-12.

essential terms (*i.e.*, FMV, commercially reasonable and volume or value of referral standards) in a purportedly circular, interconnected manner.

One commenter suggested amending the statute to provide that the FMV requirement is met where the compensation paid to the physician does not exceed FMV. Some commenters noted the confusion caused by the regulations' ambiguity on whether an arrangement that is FMV at its inception, but later falls out of FMV, continues to meet the FMV requirement. Long leases should not enjoy exception for years and short leases should not be punished if the lease falls out of FMV in six months. To address this concern, one commenter suggested that Congress could provide that arrangements that are FMV at their inception are presumed or deemed to be FMV throughout their life, up to some maximum period, such as two to three years. Alternatively, if a party obtains an FMV appraisal from a qualified, independent appraisal firm, it is entitled to rely on the appraisal for the life of the appraisal, up to a maximum of two to three years. A variation would be to specify that, in order to gain the protection of the FMV presumption or deeming, the appraisal be obtained before the arrangement begins. The commenter also recommended a similar provision for an appraisal regarding whether an arrangement is commercially reasonable.

A few commenters sought Congress's explicit confirmation that certain practices are acceptable and do not necessarily violate the Stark law. For instance, one commenter suggested that Congress confirm that DHS entities can base compensation on market surveys of similar arrangements without regard to whether those surveys involve actual or potential referral sources – given that the only available surveys involve entities (*e.g.*, medical practices, hospitals and other employers) and physicians who are in a position to make referrals. The commenter also suggested that the Stark law be amended to clearly state that nothing in the law prohibits a DHS entity from developing and using management, financial, and other reports that may include productivity or other data in their internal operations as consistent with typical business practices, so long as such reports are not used in decision-making regarding the compensation to be paid to individual physicians. Several participants at the round table suggested that Congress remove the “commercially reasonable” requirement from the employment and other compensation exceptions or clarify that operating losses in DHS entity-owned physician practices are not commercially unreasonable.

Others suggested changes to other definitions. One commenter recommended that the definition of “group practice” be revised by removing the current volume or value standard so that physicians who are part of a group practice may be paid on the basis of furnishing care without violating the Stark law. Virtually all of the exceptions to the existing Stark law impose restrictions on compensation based on “volume or value” of referrals; however, inclusion of this language in the group practice definition creates enormous confusion and opportunities for technical non-compliance. Another commenter suggested that the Stark law's definitions of remuneration and compensation arrangement be narrowed so that FMV exchanges do not implicate the Stark law.²⁷

²⁷ See [AHLA 2009 White Paper](#), at 12 (similar suggestion that compensation arrangement prohibitions apply only when payments vary with the volume or value of referrals).

Another commenter suggested Congress amend the Stark law to define reasonable safe harbors that would provide predictable refuge for hospitals that reasonably evaluate and document fair market value.

Intent. While not always tying the suggestion to the definition of technical violations, several commenters recommended that an intent requirement be added such that purely accidental omissions were not in violation of the Stark law. Some participants believed this would make the Stark law duplicative of the AKS rather than a payment rule.²⁸ Others recommended adding a harm to programs requirement to limit fines to situations where the prohibited referrals result in some demonstrable harm to the government or the patients served, with the burden of proof on the government.

Create Exception for Technical Noncompliance. One commenter recommended creating an exception for technical noncompliance based on the regulatory exception for certain arrangements involving temporary noncompliance at 42 C.F.R. § 411.353(f), but with fewer restrictions. The commenter did not specify how to differentiate between technical and substantive violations, but emphasized the importance of such an exception.

Determining the Penalty. Some commenters also advocated for the inclusion of mitigating factors when determining the penalties associated with technical violations, sometimes referring to the factors in the legislation creating the SRDP. Some commenters suggested that Congress give the Secretary explicit authority to reduce penalties or apply CMPs in lieu of penalties, and those commenters also recommended that certain factors be considered with determining the penalty amount. Suggested factors included: (1) whether the violation is technical or substantive; (2) whether the parties' failure to meet all of the prescribed criteria of an applicable exception was due to an innocent or unintentional mistake; (3) the corrective action taken by the parties; (4) whether the services provided were reasonable and medically necessary; (5) whether access to a physician's services was required in an emergency situation; and (6) whether the Medicare program suffered any harm beyond the statutory disallowance. A variation of a suggestion discussed in the previous section would be for Congress give CMS discretion to determine whether to prohibit billing for technical violations, which would allow CMS to compromise repayment amounts, to impose CMPs, or not to impose any penalty.

VII. GENERAL RECOMMENDATIONS BEYOND MACRA IMPLEMENTATION AND DEFINING TECHNICAL VIOLATIONS

Commenters noted general frustrations with Stark law compliance and explained the difficulties hospitals and other providers face in complying with the law. Several commenters noted that even if a provider fits its arrangements squarely within certain exceptions, the provider could still face lengthy and expensive legal battles because many exceptions are fact-specific. For instance, for challenges based on any Stark law exceptions with AKS/Claims Requirements, a hospital would not be able to prevail on a motion to dismiss or a motion for summary judgment because resolving the Stark law claims requires the court to also determine whether the financial relationship at issue satisfies the highly fact-specific AKS/Claims Requirements. As discussed

²⁸ See [AHLA 2009 White Paper](#), at 12 (similar comments on intent).

above, the same is true of each of the three standards (FMV, volume/value, commercial reasonable). The commenters believe that including requirements of separate laws stacks the deck against hospitals trying to obtain predictability with respect to their Stark law compliance. Although the concerns discussed below are not unique to implementing health reform, they create a chilling effect because both hospitals and physicians are wary not only of the difficulties associated with complying with the Stark law but also of the costs associated with defending even compliant arrangements.

Align Stark Law with AKS. As discussed above, many commenters believe Congress should align the Stark law and AKS. Congress (or for regulatory exceptions, HHS) could accomplish this by replacing certain Stark law exceptions with AKS exceptions. For instance, one commenter suggested that the Stark law bona fide employee exception should be made identical to the AKS bona fide employee exception, which unlike the Stark exception does not include a fair market value component. The commenter reasoned that if the concern giving rise to this exception is that part-time employees are more subject to abuse, then the Stark law's fair market value component could be limited to persons who are dually employed by a provider of DHS and a physician practice, but not be applied to physicians whose only employer is a provider of DHS. The commenter also noted that for all tax-exempt entities, there already are substantial constraints on compensation paid to employees. The commenter suggested that any compensation arrangement that satisfies an AKS safe harbor should also be exempt from the Stark law. Rather than maintaining two parallel, but not identical, sets of regulations that outline permitted practices, the commenter believes it would be better to rely on the AKS safe harbors and eliminate the separate, but not identical, exceptions to the compensation arrangements provisions of the Stark law.

Tax Exempt Exception for Compensation Arrangements. One commenter noted that the Internal Revenue Service (IRS) already limits compensation arrangements entered into by tax exempt entities, and that in light of such limitations, a potential carve out to the Stark law could be an exception applicable to any compensation arrangement that is entered into by a tax exempt enterprise. That commenter suggested that clearer, broader exceptions for bona fide co-management arrangements, professional courtesy, reasonable gifts or rewards for patient referrals, and free screenings would be helpful.

Reverse the Premise and Change the Burden of Proof. One commenter recommended reversing the premise of the Stark law to specify types of particular compensation arrangements that are "strict liability" and place the burden on government to show a violation. The commenter also recommended that penalties be made commensurate with the harm to the Medicare program. Although the structure of the Stark law has long been debated, the main argument against reversing the premise is the difficulty in defining a list of all illegal arrangements that could mask self-referrals.²⁹

Simplify/Clarify. Many of the participants suggested that the Stark law's definitions and exceptions should be streamlined and simplified. Some commenters suggested eliminating or modifying the signature requirement. One commenter recommended removing the limitation on

²⁹ See [AHLA 2009 White Paper](#), at 13.

the number of times a hospital may use the late signature rule, or in the alternative, modifying the signature requirement to simply require evidence of assent between the parties.

Other commenters recommended that the Stark law should be amended to codify CMS policy confirming that payments to physicians for personally performed services are permissible under the Stark law, even if the personally performed services are related to DHS ordered by the physician. These commenters suggest an amendment identifying the following as permissible forms of payment for personally performed services: (1) hours worked in performing such services; (2) revenues billed, collected or collectible for such services; (3) wRVUs for such services; (4) patient encounters; (5) average daily patient census; or (6) any other approach that measures the clinical or administrative services actually furnished by the physician. For every physician (whether or not in a group practice), services that are billable as “incident to” the physician’s services are deemed to be personally performed by the physician.

VIII. CONCLUSION

The Stark law was created to address a risk in an FFS payment model. The financial incentives that trigger overutilization concerns in an FFS payment model are largely or entirely eliminated in alternative payment models. Although the FFS payment model still exists, the comments show that the Stark law and its regulations have presented challenges to providers attempting to implement health care reform. Many commenters cited the Stark law’s strict liability standard and significant penalties as serious obstacles to implementing MACRA and other alternative payment reforms. The Committee appreciates all of the comments submitted and will be considering them all as we evaluate and develop potential changes to the Stark law.

Greer, Leslie

From: Glenn F. Elia <gelia@ct-ortho.com>
Sent: Tuesday, November 08, 2016 2:17 PM
To: User, OHCA; Fernandes, David; Riggott, Kaila; 'klg1@aol.com'
Subject: OCHA Docket No. 16-32117- CON Completeness Responses
Attachments: COS Completeness Answers 11.3.16.docx; Exhibit R.pdf; Combined Docs 11.3.16.pdf

Dear Ms. Riggott and Mr. Fernandez:

Attached please find the word version of the COS Responses to OHCA's Completeness Questions which were dated September 21, 2016 and a copy of Exhibit R. A copy of the completeness responses in pdf format is also attached, which consists of the responses, a revised Index, a cover sheet for Exhibit R, and the pdf version of the Exhibit R.

Please note that I have copied, Attorney Pat Gerner in on this email. I would appreciate it if Attorney Gerner could be included in all future communication between COS & OCHA regarding this application.

Please let me know if you need anything further. Thank you.

Best regards,

Glenn Elia, CEO
Connecticut Orthopaedic Specialists, P.C.

Connecticut Orthopaedic Specialists, P.C.
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner
Docket Number 16-32117-CON
Completeness Questions Responses

- Page 18 of the application states that COS orthopedic offices in the Essex area have to refer patients to other providers for MRI services due to not being able to accommodate the volume. Please provide information regarding the referrals using the tables below. Please specify the fiscal year in which the referrals were made.

Essex Service Area

Fiscal Year: 2015

Provider Name and Address	Number of Patients Referred	Distance from Essex
Middlesex Hospital dba Shoreline Medical Center ED 250 Flat Rock Place Westbrook, CT 06498	639	4.5 miles
Middlesex Hospital Outpatient Center 534 Saybrook Road Middletown, CT 06457	78	19 miles
Middlesex Hospital 28 Crescent Street Middletown, CT 06457	49	22 miles
Open MRI of Middletown 140 Main Street #7 Middletown, CT 06457	48	22 miles
Guilford Radiology 1591 Boston Post Road 106 Guilford, CT 06437	29	18 miles
Groton MRI 565 Long Hill Road Groton, CT 06340	11	23 miles
Middlesex Hospital dba Marlborough Medical Center 12 Jones Hollow Road Marlborough, CT 06447	5	26 miles
Yale MRI 801 Howard Avenue New Haven, CT 06510	6	30.7 miles
Lawrence and Memorial 196 Waterford Parkway S # 102 Waterford, CT 06385	3	17 miles
Radiology Associates of Wallingford 67 Masonic Avenue #7 Wallingford, CT 06492	3	41 miles

Provider Name and Address	Number of Patients Referred	Distance from Essex
Jefferson Radiology 1260 Silas Dean Highway Wethersfield, CT 06109	5	31 miles
Radiology Associates of Middletown 57 S Main Middletown, CT 06457	4	23 miles
Open MRI of Branford 1208 Main Street Branford, CT 06405	3	24 miles
Open MRI of Glastonbury 123 Hebron Avenue Glastonbury, CT 06033	3	36 miles
Radiology Associates of Hartford 31 Sycamore Street #102 Glastonbury, CT 06033	2	27.5 miles
Whitney Imaging 2200 Whitney Avenue #120 Hamden, CT 06518	1	38 miles
Backus Hospital 326 Washington Street Norwich, CT 06360	1	30 miles
Day Kimball Hospital 320 Pomfret Street Putnam, CT 06260	1	63 miles
Naugatuck Valley Radiology 1389 West Main Street Waterbury, CT 06708	1	46 miles
Hartford Hospital 85 Seymour Street #200 Hartford, CT 06106	1	38 miles
Madison Radiology 2 Samson Park Drive Madison, CT 06443	1	13 miles
MRI of New Britain 100 Grand Street New Britain, CT 06052	1	34 miles
St. Francis MRI 114 Woodland Street Hartford, CT 06106	1	39 miles
Manhattan Diagnostic Radiology 400 E 66 Street New York, NY 10066	1	104 miles

The above table provides information for all patients (951) who were referred by Shoreline Orthopedic and Sports Medicine to a non-COS MRI scanner in 2015. Please note that this information could not be extracted electronically from the medical records, and was compiled manually from each patient record. As a result, there is a 12 person difference between the total number of patients reported here and what was reported in Exhibit L of the CON application (963).

2. How will accessibility be improved as stated on page 19 of the application if current MRI volume is being met by other area providers?

Accessibility is more than just having an open time slot in another MRI provider schedule. COS improves our patient accessibility by working directly with each patient to accommodate to their personal schedule. COS has early morning hours at 7 am so patients can be seen before work and they are open until 9 pm for after work hours. Likewise, if a patient cannot be seen during the week, COS will open on a weekend to accommodate the patient. If a patient presents with an acute injury and there is an emergent need for MRI, COS holds daily stat slots to accommodate these patients, again providing improved accessibility over traditional radiology centers. If the patient is in pain or in a position where the injury is made worse by moving around, traveling to another office creates a situation where having the MRI scan at a different location is not as accessible as walking (or being wheeled) down a hallway within the COS office to have the MRI performed. The time delay is also a factor, as orthopedic treatment should be administered as early as possible after the injury.

Currently almost all of the patients from the Shoreline Orthopedics and Sports Medicine offices of COS, and many of the patients from the 6 COS offices in Orange, Milford and Shelton are referred to non-COS providers for MRI scans. This is due to lack of capacity of the existing scanners in Hamden and Branford, and the geographic distance of these COS scanners from the Shoreline Orthopedic offices. Accessibility will be improved because the COS patients who use the proposed 1.5T mobile MRI will be able to have the MRI scan performed in the doctor's office without having to schedule and travel to another location and without waiting longer for the results.

3. Who will staff the mobile MRI? Will the staff be the same at both locations?

One FTE receptionist and 1 FTE MRI tech will be required for services provided in the mobile MRI unit. It is anticipated that both the receptionist and MRI tech will travel to both locations. Both the receptionist and the MRI tech will be COS employees. COS will continue to utilize Dr. Joseph Gagliardi as our radiologist to read the MRI studies in the two additional locations.

4. On average, how much of a savings (with the advent of bundled payments versus traditional billing practices) have patients seen? Please quantify if possible and explain how patient savings are attained.

In numerous locations in the above-referenced CON application, the method of "bundled payments" is discussed. COS has a bundled payment program with 3 major payors for outpatient reconstructive of both total knees and hips, and is working to include all of its payors in this program.

There is a correction that needs to be brought to the attention of OHCA which was only recently discovered as the applicant prepared for OHCA's Completeness Answers. The bundled payment program does not yet include the cost of the MRI. The MRI is often utilized as part of the diagnosis, and currently the bundled payment program does not begin until the injury is diagnosed and treatment begins. As both COS and the payor community become more familiar with the intricacies of bundled payment reimbursement, which includes the collection of data for post-operative complications

and patient outcomes, it is anticipated that more services (including MRI), can be included into the bundle. As both COS and the payor community become more familiar with the intricacies of bundled payments as well as further transformation from fee for service to value based reimbursement, it is anticipated that more services, including MRI will be included in risk based payment models. As the bundle becomes more complete, with both pre-operative and post-operative services, the risk sharing between provider and payor will allow for even greater savings to the delivery system.

The existing bundled payment plan already reduces the cost for the patient and payor. The efficiency of the outpatient total joint procedures (i.e., total hip and knee replacements) has allowed the payor to lower patient deductibles associated with inpatient procedures while lowering the total cost of the surgical event by several thousands dollars as compared to the same procedure done on an inpatient basis. The savings to the patient and the payor that are incurred for these procedures are as follows:

Pre- op visit	\$50
Home visit assessment	\$250
Physical therapy 16 visits @ \$35 / visit	\$560
ASC deductible or co insurance	\$3,000
Professional fee deductible or co insurance	\$1,995
Anesthesia fee deductible or co insurance	\$1,020
Pain block fee deductible or co insurance	\$420
DME deductible or co insurance	<u>\$100</u>
TOTAL	\$7,395

5. Provide the percentage of patients with insurance plans that accept bundled payments versus traditional billing practices.

Presently, the patients in COS who are under the bundled payment program make up approximately 3%. This is due to the fact that bundled payment programs are new and COS is the only practice in CT that is providing outpatient total joint procedures under a bundled payment arrangement. As healthcare reimbursement transitions from fee for service to pay for performance, capitations and bundled payment programs, it is anticipated that the percentage will increase in a dramatic fashion.

6. How will the addition of a mobile MRI scanner in Orange and Essex improve the quality of health care for the Medicaid population?

COS accepts Medicaid recipients at all of its offices and facilities; COS does not discriminate patients based on insurance type or ability to pay. The availability of MRI service in Orange and Essex at the physicians' offices will enhance the ability of all patients to access this necessary diagnostic modality. The MRI service is managed by Dr. Gagliardi, a board certified radiologist, who is able to read the MRI scan and report the findings back to the treating physician within the same day, but no later than 24 hours after the scan. The short time between the MRI scanning and the orthopedic physician's ability to start treatment makes an enormous difference in the quality of health care provided. While this service will only be available two days a week in both locations, it will allow more COS patients (Medicaid and all others) to take advantage of a seamless health care service.

7. Please explain why the equipment cost shown on Table 3 (p. 41) is not included in the total project cost and why the total expenditure does not match the expenditure in the newspaper notice (p. 5).

The estimated costs for the installation of the MRI trailer at the Orange and Essex locations were revised subsequent to the publication of the newspaper notice which listed a capital expenditure of \$675,000. At the time of the publication the installation costs were projected to be \$100,000 and the revised estimate increased the costs by \$35,000 to \$55,000. Therefore, the costs now range from \$135,000 to \$155,000. We have used the higher installation estimate in projecting the project costs. Additionally, a clerical error occurred in the completion of Table 3 as submitted in the CON application. The corrected Table 3 follows. Copies of the purchase agreement for the MRI unit and trailer with MedExchange International, Inc., and an estimate for the trailer installation by Kingsbrook Development Corp. are found in Exhibit M of the CON application, starting on page 199.

**REVISED TABLE 3
TOTAL PROPOSAL CAPITAL EXPENDITURE**

Purchase/Lease	Cost
Equipment (Medical, Non-medical, Imaging)	\$575,000
Land/Building Purchase*	
Construction/Renovation**	\$155,000
Other (specify)	
Total Capital Expenditure (TCE)	\$730,000
Lease (Medical, Non-medical, Imaging)***	0
Total Lease Cost (TLC)	0
Total Project Cost (TCE+TLC)	\$730,000

* If the proposal involves a land/building purchase, attach a real estate property appraisal including the amount; the useful life of the building; and a schedule of depreciation.

** If the proposal involves construction/renovations, attach a description of the proposed building work, including the gross square feet; existing and proposed floor plans; commencement date for the construction/ renovation; completion date of the construction/renovation; and commencement of operations date.

*** If the proposal involves a capital or operating equipment lease and/or purchase, attach a vendor quote or invoice; schedule of depreciation; useful life of the equipment; and anticipated residual value at the end of the lease or loan term.

8. Why was there a drop in MRI volume at the Branford facility in FY2013?

The drop in MRI Branford volume at the Branford facility was multi-faceted. Problems existed with the 1T MRI unit that was located in Branford and it was replaced at the end of 2013. There were several significant down time periods throughout 2013 when the unit was out of commission, and patients were either referred to COS MRI unit located in Hamden or other facilities. In December of 2013, the 1T unit was replaced with a refurbished 1.5T GE magnet. This installation took 2 weeks and resulted in additional loss of patient volumes.

9. Why was FY 2015 the sole year used to project the service area given that Branford volume was significantly lower the previous three years?

Between 2014 and 2015, COS merged with four (4) other orthopedic physician group practices. (See CON App., Q. #1, p.16). This merger expanded the total number of physician offices from 8 to 21 for a practice that now has 49 physicians. Patient volume increased from 6,302 scans in FY 2014 to 7,624 scans in FY 2015. The significant expansion of COS in 2014 - 2015 is the primary reason that a second MRI is needed. This volume is not expected to go down in the future because of the large increase of physicians in the COS practice. Therefore, FY2015 is a true reflection of COS patient volume because it reflects the expanded size of COS. It was selected as the base year because it was the most recently completed FY, and the number of scans is actual, not projected.

The four practices that merged with COS are Center for Orthopedics, Shoreline Orthopedics and Sports Medicine, The Orthopedic Group and Orthopedic Health. The merger and resultant increase in the number of COS physicians resulted in a significant increase in the number of MRI scans in 2014, 2015 and projected for 2016. Both of the existing COS scanners (located in Branford and Hamden) experienced increases in the number of scans, all related to the expansion of COS.

10. Please provide articles or patient satisfaction surveys that demonstrate the quality of a mobile MRI?

There are no articles that speak specifically to mobile MRI units. The reality is that there is no difference between a "fixed" MRI vs. a mobile MRI. Both units are 1.5 T in magnet strength. The only difference is that a mobile unit is located within a tractor trailer and is therefore capable of being moved from one location to another. There is no difference in the resolution of the MRI study. The patient experience is essentially the same because the units are identical in capability.

Both existing COS "fixed" MRI scanners have received accreditation from the American College of Radiology (ACR). ACR accreditation will be obtained for the proposed mobile MRI scanner if approved. (CON App., p. 22 and Exhibit H).

11. How would the operation of the proposed mobile MRI conform to the intent of federal law? (Stark)

The proposal meets the in-office ancillary services ("IOAS") exception that is provided to group practices under the Stark law.

The Stark Law, 42 USC §1395nn(a)(1)(b), prohibits a physician from making a referral to a Designated Health Services entity ("DHS entity") for the furnishing of designated health services that would otherwise be covered by Medicare if the physician (or an immediate family member) has a financial relationship with the entity, unless an exception applies 42 USC § 1395nn(a)(1)(b).

The exceptions include the In-Office Ancillary Services (“IOAS”) exception, which allows radiology services such as MRI to be performed within a physician group as long as certain requirements are met. The Applicant, COS, complies with all of the Stark requirements in order to meet the demands of the exception to the general rule.

This is the current law in effect, and there does not appear to be any intent on the part of Congress to eliminate the In-Office Ancillary Services exception. To the contrary, there has been discussion that many of the Stark restrictions are impeding the ability to lower the cost of health care – and as a result, some of the restrictions should be eliminated. In December of 2015, the Senate Committee on Finance and the House Committee on Ways and Means invited a group of subject-matter experts to participate in a round table discussion on issues related to the physician self-referral rule, section 1877 of the Social Security Act, 42 U.S.C. § 1395nn. “Support for Stark law reform has grown in recent years, and following the enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”), Pub. L. No. 114-10 (2015), and other health care reforms, the case for reforming the Stark law has become stronger.” See Senate Finance Committee Majority Staff Report, “Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models” Exhibit R, p. 1.

This “white paper”, published after round table discussions on issues related to the physician self-referral law, stated, “The Stark law has become increasingly unnecessary for, and a significant impediment to, value-based payment models that Congress, CMS, and commercial health insurers have promoted. The risk of overutilization, which drove the passage of the Stark law, is largely or entirely eliminated in alternative payment models.” Exhibit R, p. 2. The case is being made to eliminate the Stark Law completely, not to eliminate the In-Office Ancillary Exception.

While there is still debate about whether to eliminate or restructure the Stark Law in the future, at this time the In-Office Ancillary Service exception is still the law, and the Applicant, COS, conforms to this federal law.

Revised Exhibit List

Exhibit	Description	Pages
A	Map of COS Locations; List of COS Office Addresses; and List of All COS Physicians.	59 - 68
B	Graphs of Increased MRI Scanning in Hamden and Branford FY 2013 - 2016.	69 - 72
C	DPH License for Outpatient Surgery Center in Branford.	73 - 74
D	List of Key Professional, Administrative, Clinical and Direct Service Personnel and Curriculum Vitae	75 - 91
E	Scholarly Articles	92 - 122
F	Letters of Support	123 - 130
G	COS Standard of Practice Guidelines	131 - 171
H	American College of Radiology Accreditation for Existing MRI Scanners	172 - 174
I	COS Charity Care Policy	175 - 176
J	Target Populations: Patient Zip Codes	177 - 193
K	FY2015MRI Scans in the Essex Area for COS Patients	194 - 196
L	FY2015MRI Scans in the Orange Area for COS Patients	197 - 198
M	Capital Expenditures for Mobile MRI	199 - 203
N	Funding or Financial Resources for the Project	204 - 207

O	COS Financial Statements; Balance Sheets and Related Income Statements for FY 2014 and 2015	209 – 213
P	Financial Worksheet	214 – 215
Q	Assumptions Used in Financial Worksheet	216 – 218
R	Senate Finance Committee Majority Staff Report, “Why Stark, Why Now?”	228 - 248

EXHIBIT R

Why Stark, Why Now?

Suggestions to Improve the Stark Law to Encourage
Innovative Payment Models



A Senate Finance Committee Majority Staff Report

Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models

Senate Committee on Finance, Majority Staff
Chairman Orrin Hatch (R-Utah)

I. INTRODUCTION

On December 10, 2015, the Senate Committee on Finance and the House Committee on Ways and Means invited a group of subject-matter experts to participate in a round table discussion on issues related to the physician self-referral law, section 1877 of the Social Security Act, 42 U.S.C. § 1395nn, also known as the Stark law.

The Stark law prohibits a physician from referring Medicare patients for “designated health services” (DHS) to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies.¹ Financial relationships include both ownership and investment interests, as well as compensation arrangements. In addition, the law prohibits an entity from billing the Medicare program for services provided pursuant to an impermissible, or tainted, referral.

Support for Stark law reform has grown in recent years, and, following the enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Pub. L. No. 114-10 (2015), and other health care reforms, the case for reforming the Stark law has become stronger. The strict liability regime, huge penalties, and the breadth, complexity, and ambiguities of the Stark law and its regulations have created what is often referred to as a minefield for the health care industry. With this backdrop, attempts by Congress, the Centers for Medicare & Medicaid Services (CMS), and the private sector to encourage value-based payment models have not effected change as quickly as some had hoped. While many providers would like to move toward alternative payment models, most are reluctant to do so because they must contend with the tension between the Stark law and alternative payment models and the possibility of devastating penalties if they guess wrong.

The round table participants discussed whether changes to the law were necessary to implement MACRA and, if so, what options would work best in a system that includes both the fee-for-service (FFS) payment model and alternative payment models. After the meeting, the Committees invited the round table participants and others to share their views on the Stark law.²

The round table participants and the groups that submitted comments for the Committees’ review included Stark law experts, academics, attorneys in private practice who work with

¹ Section 1903 of the Social Security Act, 42 U.S.C. § 1396b, prohibits payment of the federal share of Medicaid to states for services paid under Medicaid that would have constituted a prohibited referral under Medicare.

² In 2009, the Public Interest Committee of the American Health Lawyers Association (AHLA) sponsored a “Convener on Stark law” (Convener Session) held on April 24 and June 30, 2009, in Washington, D.C. A white paper was published entitled, [A Public Policy Discussion: Taking the Measure of the Stark Law](#), which summarizes the discussion and proposals for changing the

hospitals and/or physicians, attorneys in the private sector who previously served in government regulatory and enforcement agencies, hospital systems, electronic health record providers, as well as associations representing hospitals, physicians, medical device manufacturers, accountable care organizations, and several types of ancillary service providers.

II. EXECUTIVE SUMMARY

Congress enacted the Stark law to limit the influence of financial relationships on physician referrals. If a physician (or an immediate family member) has a financial relationship with an entity, then the physician may not make a referral to the entity for the furnishing of DHS under Medicare and, to some extent, Medicaid, unless an exception applies. 42 U.S.C. § 1395nn; 42 U.S.C. § 1396b. A “financial relationship” is defined as any direct or indirect (1) ownership or investment interest or (2) compensation arrangement by or between a physician (or an immediate family member of the physician) in the entity providing the DHS. An entity may not bill for DHS provided as the result of a tainted referral.

Congress intended the Stark law to provide a bright line test to curb physician self-referral. But despite CMS’s efforts to provide clear rules and interpretations to address the strict liability regime, the Stark law’s breadth, complexity, and impenetrability have created a minefield for the health care industry. As Judge James A. Wynn of the United States Court of Appeals for the Fourth Circuit noted last year, “even for well-intentioned health care providers, the Stark law has become a booby trap rigged with strict liability and potentially ruinous exposure – especially when coupled with the False Claims Act.” [United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.](#), No. 13-2219, 2015 U.S. App. LEXIS 11460 at *56, *69 (4th Cir. July 2, 2015) (Wynn, J., concurring).

The Stark law has become increasingly unnecessary for, and a significant impediment to, value-based payment models that Congress, CMS, and commercial health insurers have promoted. The risk of overutilization, which drove the passage of the Stark law, is largely or entirely eliminated in alternative payment models. When physicians earn profit margins not by the volume of services but by the efficiency of services and treatment outcomes, their economic self-interest aligns with the interest to eliminate unnecessary services. Before Congress passed health care reform, the health care industry recognized that the Stark law would be an obstacle to hospitals’ and other providers’ efforts to align incentives with physicians for certain alternative payment models, including pay-for-performance, gainsharing, bundled payment or outcomes measures. During the American Health Lawyers Association’s (AHLA) 2009 Stark discussion, many participants noted that alternative payment programs inevitably link physician payments to

law itself or its administration or enforcement. Although the topics covered do not overlap precisely, our December 2015 round table was an effort to look at what changes had taken place since 2009, given the passage of the Affordable Care Act in 2010 and MACRA in 2015. The views shared by the round table participants and subsequent commenters reflect the changing legal landscape between 2009 and the present, but they also echo many of the underlying issues discussed in the 2009 AHLA session.

the volume or value of physician referrals³ – a payment formula that generally will not pass muster under the compensation arrangement exceptions to the Stark law.⁴

Congress also recognized that alternative payment models would be difficult or impossible to establish in the current FFS enforcement environment. As a result, the Affordable Care Act (ACA) included an authorization for the Health and Human Services (HHS) Secretary to issue regulatory waivers from the Stark law and other fraud and abuse laws for innovative payment and service delivery models.⁵ Under that authority, the Secretary has issued waivers from fraud and abuse laws for participants in the Medicare Shared Savings Programs (MSSP), the Bundled Payments for Care Improvement Initiative (BPCI), the Comprehensive Care for Joint Replacement (CJR), and other Accountable Care Organization (ACO) programs.

MACRA's modification of the Civil Monetary Penalties (CMP) law, 42 U.S.C. § 1320a-7a, (specifying that the gainsharing prohibition applies only to inducements made to reduce or limit medically necessary services to beneficiaries) has removed some barriers to gainsharing and pay-for-performance programs. Nevertheless, as the waivers for CMS demonstrations illustrate, the Stark law continues to pose significant risks for implementation of such programs. Importantly, Medicare waivers do not protect all alternative payment models under MACRA or with commercial payers, undercutting hospitals' ability to provide uniform and consistent incentives for physicians across all patient populations.

The Committees invited the round table participants to consider an array of known issues, including the current Stark law environment, health care reform implementation, costs associated with compliance and disclosures, possible fixes under both FFS and alternative payment models, and CMS's limited authority to create exceptions and to issue advisory opinions. Round table participants were then asked to specifically focus on (1) changes to the Stark law to implement health care reform, specifically MACRA, and (2) the distinction between technical and substantive violations.

Although the comments that we received were wide-ranging, there were many recurring themes. To implement health care reform, many comments focused on potential new waivers or exceptions, expansion of existing waivers or exceptions, broadening CMS's regulatory authority, repealing the compensation arrangement prohibition, or repealing the law in its entirety. Comments also concentrated on other important non-MACRA issues, including changes to standard Stark law definitions, like fair market value, the volume and value of referrals, and commercial reasonableness. In distinguishing technical and substantive violations, comments centered on documentation requirements and harm to beneficiaries or federal health care programs.

³ Reducing unnecessary FFS procedures or services reduces costs but increases profit (*i.e.*, value).

⁴ AHLA, [A Public Policy Discussion: Taking the Measure of the Stark law](#), at 9 (2009) (hereinafter, [AHLA 2009 White Paper](#)).

⁵ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3022, (2010).

Some commenters submitted other suggestions for improving the law, including changes or clarifications to in-office ancillary services exception, the physician-owned hospital exception, documentation requirements, and others. This white paper focuses on potential changes to the Stark law to remove hurdles to implementing health care reform and on how to distinguish technical and substantive violations. The other issues that are not addressed in detail in this white paper may be considered by the Committee at a future point in time.

III. STARK LAW BACKGROUND

Under an FFS payment model, physicians have a financial incentive to provide more services. When a physician has a financial interest in an entity to which he or she refers patients, the incentive extends to ordering tests, procedures, or referring patients to that entity. The issue received attention in the 1980s, and, by 1989, the HHS Office of Inspector General found that physician self-referral related to laboratory tests was associated with a marked increase in utilization.⁶

That year, Congress passed the Ethics in Patient Referrals Act of 1989 (Stark I) prohibiting a physician (or an immediate family member) who had a financial relationship with a clinical laboratory services entity from referring Medicare beneficiaries to the entity, unless an exception applied. Stark I also prohibited the lab from billing for any services furnished pursuant to a tainted referral. To prevent the law from being circumvented by contractual structures that did not involve equity but gave physicians the benefits of ownership, Congress also prohibited circumventions schemes and compensation arrangements. Stark I became effective January 1, 1992. Congress soon expanded the clinical laboratory prohibition to ten “designated health services” in the Omnibus Budget Reconciliation Act of 1993 (Stark II), which became effective January 1, 1995. Stark I and Stark II each included exceptions to the general prohibition.

CMS has published a series of regulations implementing the Stark law, beginning in 1992.⁷ The final rules, listed below, are codified at 42 C.F.R. § 411.350–411.389.⁸

- Stark I regulations, August 14, 1995.
- Stark II Phase I regulations, January 4, 2001 (interim final rule).
- Stark II Phase II regulations, March 26, 2004 (interim final rule).
- Stark II Phase III regulations, September 5, 2007.
- Stark II Phase IV, Inpatient Prospective Payment System (IPPS) regulations, August 19, 2008.
- Stark II Phase V, IPPS regulations, October 30, 2015.

⁶ OIG-Office of Analysis and Inspections, Report to Congress, [Financial Arrangements Between Physicians and Health Care Businesses](#), 3 (May 1989).

⁷ AHLA’s [2009 White Paper](#) includes a chart with a helpful description of the regulatory changes from 1992 through 2009, at pages 4-5.

⁸ The CMS website has a list detailing the Stark law’s [significant regulatory history](#).

Several commenters stated that the Stark law is not a “fraud” statute, but a regulation of payment. There is no requirement of an intent to violate the statute and compliance is a straightforward condition of payment. These commenters noted that Congress intended to provide a bright line rule, which would encourage hospitals and other providers to self-police their arrangements with physicians.

Even with regulatory exceptions and guidance, the result has been an extremely broad prohibition on physician referrals. If a physician has a financial relationship with an entity, any referrals by the physician to that entity are prohibited unless the financial relationship fits within one or more exceptions.⁹ But the round table participants characterized the exceptions as illusory because the three key standards in most exceptions—fair market value, “takes into account” volume or value of referrals, and commercially reasonable—are factual, which means parties must prove that their arrangement fits into the exception at trial. Moreover, the participants and commenters noted that the three standards are ambiguous, and thus lead to unpredictable outcomes. The unpredictability is especially frustrating given the enormous penalties under the Stark law, which can be much higher than penalties for fraudulent activity.¹⁰

Commenters also noted the high cost and difficulty of complying with the Stark law. Even tracking non-monetary compensation issues can cause headaches for hospitals and physicians. For instance, if a physician agrees to join an ACO, it makes sense to provide access to the same electronic health record system used by the rest of the network. While the current MSSP waivers address this concern, if the physician leaves the ACO, or when the waivers expire, the physician may face Stark liability, which is just one additional hurdle to physicians joining ACOs and other integrated health care entities.

Some participants noted the law’s inflexibility, as it prohibits any financial arrangement with a physician that does not fit within an exception. This inflexibility is underscored as providers attempt to implement alternative payment models like ACOs, pay-for-performance, shared savings, and bundled payments, which do not always fit into existing exceptions. Participants and commenters generally agreed that the Stark law does not have a place in the pay-for-value world because it was created to address overutilization in an FFS environment. Many participants and commenters believe that the law is disruptive to the development and implementation of value-based models.

⁹ The requirement that the financial relationship fit within an exception is different than the option to fit a relationship within a safe harbor to the Anti-Kickback Statute (AKS). Under the AKS, financial relationships that do not fit squarely within a safe harbor do not necessarily violate the AKS.

¹⁰ If a hospital has a non-compliant financial arrangement with a physician, all Medicare payments for all inpatient or outpatient services from that physician are “overpayments” and must be returned, regardless of the amount of the “tainted” transaction or nature of the payment. In contrast, even the new authority in the ACA expanding the false claims liability for violations of the AKS is limited to claims “resulting from” the kickback.

Although many areas for improvement were discussed, especially those to usher in health care reform, round table participants and commenters also recognized that the Stark law has been effective in restricting physician ownership and investment in entities such as free-standing imaging centers and other providers of ancillary services. The law has also encouraged the industry to focus on compliance because of the need to closely scrutinize physician relationships, but several commenters noted that in practice the burden of compliance falls upon hospitals. Round table participants praised the establishment of the Self-Referral Disclosure Protocol, which enables providers to disclose Stark violations and permits CMS to compromise repayment amounts. Some participants noted that the settlements under the Protocol have been fair and reasonable. But several participants believe that the process is too time consuming and does not provide certainty to disclosing parties. Some commenters point to exceptionally high settlements for disclosures of technical violations based on documentation issues alone.

IV. STARK LAW IN CONTEXT

Round table participants and commenters discussed the Stark law in the context of other enforcement authorities and reimbursement rules that may also address physician self-referral practices.

Anti-Kickback Statute. Many commenters noted the imperfect and often confusing overlap between the Anti-kickback statute (AKS), 42 U.S.C. § 1320a-7b, and the Stark law.¹¹ Relationships that are permissible under the Stark law may violate the AKS, which some commenters said means the Stark law occasionally undermines the enforcement of the AKS. When Congress passed the Stark law, there was no civil liability for anti-kickback violations under the CMP law, and it was unclear whether the government could use an anti-kickback violation as a predicate for a False Claims Act (FCA) case.

With the expansion of the scope and application of the AKS over the years, however, many participants and commenters argue that the Stark law is no longer needed. The AKS can now be enforced in the civil context through the FCA and the CMP law. Not all participants agreed that the Stark law was no longer needed, in part because the FFS payment model would still be used to some extent for years to come.

Compounding the complicated overlap between these two statutes, is the disproportion in penalty levels. Penalties are smaller for AKS violations, which require knowing and willful intent, meaning the underlying conduct is arguably much more egregious.

False Claims Act. The FCA has become the primary enforcement mechanism of the Stark law. 31 U.S.C. § 3729–3733. While the Stark law prohibits physician referrals to an entity based on non-compliant financial relationships, from an FCA perspective, the focus is on the prohibition on billing for services furnished pursuant to a tainted referral. FCA exposure is created if the claims were submitted with the requisite intent (reckless disregard or deliberate

¹¹ While this may be an area that would benefit from further examination by Congress, the AKS is outside the Finance Committee’s jurisdiction, and while we may refer to comments that mention the AKS, we are unable to address those concerns at this time.

ignorance of their truth or falsity). The Fraud Enforcement and Recovery Act of 2009 (FERA) expanded the potential for FCA exposure by revising the definition of a claim to include the knowing and improper retention of an overpayment.¹² 31 U.S.C. § 3729(a)(1)(G). In 2010, the ACA added the “60-day rule” requiring providers to “report and return” a Medicare or Medicaid overpayment within 60 days “after the date on which the overpayment was identified.” 42 U.S.C. § 1320a-7k(d)(1)–(3). Thus, under the FCA’s reverse false claims provision, an entity that submits a claim with no knowledge that it may be prohibited by the Stark law may face FCA exposure if (1) the entity later discovers the Stark violation and (2) fails to report and return any reimbursement associated with the tainted claim within the 60-day period.¹³

Some commenters expressed concerns with recent FCA litigation, noting that certain aspects of the Stark law have led to a number of recent FCA settlements that threaten the development of integrated delivery systems. The commenters pointed to several recent FCA settlements based on a *qui tam* theory that an accounting loss for hospital-owned physician practices is *ipso facto* evidence that the employed physicians are paid more than fair market value and that the arrangement is not commercially reasonable. The commenters acknowledge that the complaints for some of the recent settlements may involve extreme facts but are nonetheless concerning as potential examples of bad facts making bad law.

Reimbursement. Some round table participants noted that reforming reimbursement rules may address the Stark law’s underlying concern of overutilization. Some suggestions included decreasing reimbursement for ancillary services provided through a physician’s group practice, bundling the payment for physician office visits and ancillary services, and adopting bundled payment plans that promote shared risk among providers involved in an episode of care.¹⁴ Although we did not receive comments in direct opposition to these suggestions, we received numerous comments both in favor of and against any changes to the in-office ancillary services exception which could serve as an alternative to payment changes for such services.

V. IMPLEMENTING MACRA AND OTHER ALTERNATIVE PAYMENT MODELS

As noted above, the Committees invited round table participants and others to share their perspectives on what changes to the Stark law might be necessary to implement health care reforms promoting alternative payment models, such as MACRA. Participants were asked to

¹² Prior to FERA, liability for retention of an overpayment required an affirmative step to evade repayment through a false record or statement and only if it could be established that repayment was an “obligation.” This provision became known as a reverse false claim.

¹³ In rejecting two motions to dismiss, the District Court for the Southern District of New York recently addressed what it means to “identify” an overpayment and start the clock for the 60-day rule under the FCA. *U.S. ex rel. Kane v. Healthfirst, Inc., et al.*, No. 11 CIV 2325, 2015 U.S. Dist. LEXIS 101778 (S.D.N.Y. Aug. 3, 2015).

¹⁴ For additional reimbursement suggestions shared during AHLA’s Convener Session, see, [AHLA 2009 White Paper](#), at 12.

include in their suggestions options that would work in a payment environment that includes both FFS and alternative payment models.

The comments generally focused on potential new waivers or exceptions, expansions of existing waivers or exceptions, changes to standard Stark law definitions, broadening the Secretary's authority, or repealing the law or the compensation arrangement prohibition. The relevant comments are summarized by category below.

Repeal. Many commenters suggested that the Stark law has outlived its utility. These commenters argue that the AKS in its current form can address the conduct that the Stark law seeks to curtail. However, some commenters noted that the Stark law addresses conduct that may not fall under the AKS. Additionally, while the FFS payment model is being phased out, it will continue in some form for many years. With this in mind, some commenters advocating repeal recommended that the Stark law be sunset once Medicare had transitioned to alternative payments to a meaningful extent.

Repeal Compensation Arrangement Prohibitions. A larger group of commenters believed that repealing the compensation arrangement requirements would address many of the concerns not only with implementing health care reform but with the Stark law's most difficult provisions. They recommend limiting the Stark law to ownership and investment interests, which they believe was Congress's original intent. However, as some commenters noted, prohibitions on compensation arrangements have been in the law from the beginning and were included to avoid schemes to circumvent the law with creative arrangements that would give physicians the benefits, and dangers, of ownership but that did not involve equity.¹⁵ Other commenters argued that the compensation arrangement prohibitions are no longer necessary because the AKS can now be enforced in a civil context through both the FCA and the CMP law.

New Risk Revenue Waiver/Exception. To lessen the burden of health care entities making the transition from FFS to alternative payment models, two commenters recommended creating a waiver from the Stark law once a health care entity's risk revenue reaches a certain majority percentage of its total revenue. Health care entities receiving such a waiver would be required to meet certain criteria, for example, having the governing board of the ACO entity approve applicable financial relationships through a process that validated Triple Aim¹⁶ principles and shows no motivation to increase utilization. Noting that some health care entities would never reach this level of risk based revenue, one of the commenters acknowledged that entities that did not reach such a level of risk engagement would still be required to meet a Stark

¹⁵ [AHLA 2009 White Paper](#), at 12.

¹⁶ See Donald M. Berwick, et al., [The Triple Aim: Care, Health, And Cost](#), Health Affairs, May/June; 2008, 27(3) at 759-769. "The Triple Aim is a framework developed by the Institute for Healthcare Improvement that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimensions, which we call the "Triple Aim": Improving the patient experience of care (including quality and satisfaction); Improving the health of populations; and Reducing the per capita cost of health care." IHI website, [Triple Aim Initiative](#).

exception for certain arrangements. The other commenter framed the exception in terms of health care systems that derive no less than 50 percent of their health care revenue from alternative payment methodologies, and recommended that such systems receive a broad waiver from the Stark law similar to those now in effect for ACOs.

The commenters believe that enforcement agencies could use the AKS and the gainsharing CMP to address problematic arrangements. This idea accommodates the incremental transition to value-based payment models. However, some round table participants questioned how health care entities could reach a threshold percentage without being at risk, arguing that this type of fix would simply shorten the period of exposure for a subset of providers.

Create New or Expand Currently Restricted Waivers. Most commenters suggested extending the waivers that are currently highly limited to CMS-run programs to all payers. Many commenters believed that expanding the waivers for the MSSP to qualifying alternative payment model participants would be the best solution.¹⁷ Some urged that the same protections be provided to physicians operating in alternative payment models that were provided through ACOs eligible for MSSP, including the pre-participation period. Those commenters believe this would recognize the variety of alternative payment models that use different mechanisms and structures to encourage efficient care. One commenter stated that, ideally, Congress would make the current Center for Medicare & Medicaid Innovation (CMMI) waivers permanent and available to all new adopters of similar models in the future, as well as permanent programs established under the CMMI's authority.

Commenters agreed not only that Congress should create waivers to address the problem but also that Congress should give HHS broader authority to create regulatory waivers. While commenters generally agreed that some new waivers could be created through existing but limited CMS rulemaking authority, most agreed that Congress should give CMS express authority to create broader waivers than currently authorized by law.¹⁸

Some commenters argued for consistency in fraud and abuse laws' applicability to ACO programs for all government-supported innovative payment models. One suggestion to accomplish such consistency was the creation of a new Stark law exception at 42 U.S.C. § 1395nn(b) that would apply to MIPS, physician-focused payment models, and payments associated with alternative payment models. Another suggestion was to create a waiver that would apply to MIPS, alternative payment models, and ACOs, modeled on current Stark exceptions for Medicare prepaid plan enrollees. These type of waivers could address issues in an environment that includes both FFS (MIPS) and alternative payment models.

¹⁷ CMS and OIG, HHS, [Medicare Program; Final Waivers in Connection With the Shared Savings Program, 80 Fed. Reg. 66,726](#) (Oct. 29, 2015) (codified at 42 C.F.R. Chs. IV and V).

¹⁸ Recommendations to expand the Secretary's authority to create waivers and exceptions are discussed below.

Create New Exceptions. Many commenters suggested the creation of a new exception to enable financial arrangements that involve risk-sharing and gainsharing in alternative payment models when appropriate safeguards are in place. Some recommended that such an exception (the “APM Exception”) apply to all MACRA alternative payment model financial arrangements and expressly allow for compensation arrangements that take into account the volume or value of referrals, and that it not impose a fair market value requirement. At least one commenter recommended a new exception for quality-based payments to physicians, provided that such payments are not tied to the volume or value of referrals.

Other commenters stated that a new exception should be available for financial relationships designed to foster collaboration in the delivery of health care and incentivize and reward efficiencies and improvements in care (referring to integrated delivery systems, accountable care, team-based care, or value-based payment arrangements). Some commenters, concerned that an exception may focus on institutional providers, expressed the need for an exception that took into account the breadth and scope of providers and entities necessary for truly integrated health care. Other commenters emphasized that the new exception should be available for truly clinically integrated arrangements designed to achieve the efficiencies and care improvement goals of new payment models. Commenters also noted the need to protect shared savings and incentive programs, as well as any arrangement start-up or support contribution, when certain conditions are met.

One commenter suggested an approach to accommodate alternative payment models, either under MACRA or more broadly, that would involve adding an additional statutory exception for alternative payment models that promote and advance accountability for quality, cost/risk, care coordination, patient experience, and outcomes. To qualify for the exception, which could be added to the compensation arrangement exceptions at 42 U.S.C. § 1395nn(e), arrangements would need to meet conditions that are already used to qualify ACOs and other risk-sharing arrangements under the Stark law and AKS. These safeguards include written agreements, transparency, and provider accountability, as well as prohibitions on double billing or shifting costs to federal health care payers.

Special Compensation Rule. The majority of comments touched on potential changes to how the Stark law treats compensation arrangements. As an alternative to an integrated delivery system waiver, some commenters recommended changing the fair market value requirement or the fair market value definition to accommodate alternative payment models. One commenter suggested a special compensation rule related to MACRA alternative payment model financial arrangements that would automatically deem such arrangements to (1) not take into account the volume or value of referrals, or other business generated between the parties, and (2) constitute fair market value, provided all MACRA alternative payment model programmatic requirements were otherwise met.

Modify Existing Exceptions. Commenters also suggested modifying existing statutory or regulatory exceptions to the Stark law to promote integrated care and aligned incentives.

Most Stark law exceptions protect a “financial relationship” and except the relationship from triggering the prohibition on DHS referrals. Other exceptions, like the prepaid plan exception at 42 U.S.C. § 1395nn(b)(3), only protect the services that would otherwise be

prohibited DHS referrals. The prepaid plan exception, for example, only protects referrals of services to the prepaid plan but still prohibits FFS referrals to the same party. Several commenters recommended Congress broaden the statutory prepaid plan exception so that the prohibition on referrals for DHS would not apply to services rendered by an entity that has a contract with CMS or its agent that contemplates the use of alternative payment models. Alternatively, the exception could be framed so that it protects DHS furnished to a Medicare beneficiary who is assigned to an MSSP, Pioneer, or Next Generation ACO, or any other ACO model established by CMS or tested under CMMI. Either scenario should protect services that would otherwise be prohibited DHS referrals; FFS referrals to the same party would still be prohibited. These commenters argue that this would provide more certainty for the regulated community than an extension of the regulatory waiver approach for ACO arrangements.

Several commenters recommended Congress expand the risk-sharing exception at 42 C.F.R. § 411.357(n) to apply to Medicare and Medicaid FFS programs. Other commenters would expand the exception to incentive payment arrangements between a DHS entity and a physician participating in a qualified alternative payment model (others framed this as applying to compensation arrangements involving integrated care organizations). Some commenters recommended that a new exception be created based on the risk-sharing exception that would apply to MSSP, Pioneer, Next Generation ACO, or other CMS or CMMI ACO models, as long as the arrangement is reasonably related to one of the purposes of the respective program. The exception would explicitly cover payment arrangements that are downstream of bundled payments, shared savings, and other alternative payment programs implemented by governmental or private payers. Commenters advocated for consistency between the Stark law and the CMP law, stating that the Stark law should not prohibit any arrangement presently permitted under the CMP law, as amended by MACRA, specifically the modifications to the gainsharing prohibition. They also recommended a clarification that the volume and value standard under the Stark law is not implicated when a physician is incentivized to follow a standard hospital quality measure (*e.g.*, a care protocol) that includes ordering an item or service for a patient that will not result in any additional reimbursement to the hospital.

One commenter recommended Congress codify the existing exception applicable to services furnished by an organization (or its contractors or subcontractors) to enrollees set forth at 42 C.F.R. § 411.355(c), and modify it to incorporate alternative payment models, including those involving integrated care organizations, as being eligible for protection.¹⁹

Another commenter noted that although the current Stark rules do not pose major obstacles for parties to enter into bundled payment or gainsharing arrangements, some legislative changes or clarifications to the Stark law could provide much needed comfort for parties who are uncertain how to proceed or fear inappropriate enforcement efforts.

One area the commenter identified for clarification is the definition of an indirect compensation arrangement, which, along with the exception for indirect compensation

¹⁹ For purposes of consistency, the commenter recommended that the definitions of health plan and enrollees under 42 C.F.R. § 1001.952(1) be modified to contemplate ownership and compensation relationships arising out of alternative payment models.

arrangements, is one of the most complex and frustrating areas of Stark regulation. The definition includes three components. One of those components is based on the referring physician's receipt of aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS. *See* 42 C.F.R. § 411.354(c)(2)(ii). The commenter recommends that Congress clarify that where the physician's compensation from an entity with which he or she has a direct compensation arrangement does not necessarily rise as a direct result of more referrals or higher paying referrals, the aggregate compensation test is not met.

Additionally, the commenter notes that although arrangements where physicians are paid a percentage of savings are common, CMS has never expressly recognized that a percentage of savings can be fair market value and commercially reasonable. To resolve uncertainty and to promote non-abusive shared savings arrangements, the commenter recommended that Congress adopt CMS's deeming provision for per-click compensation arrangements, 42 C.F.R. § 411.354(d)(2), and extend it to percentage compensation arrangements. The commenter also recommended that Congress amend the Stark law to state that an arrangement under which a physician receives a percentage of saving realized by a provider can satisfy the fair market value and commercial reasonableness requirements of an applicable exception. Alternatively, Congress could provide that an arrangement under which a physician would receive a percentage of savings realized by the hospital or other provider or supplier will be presumed (or deemed) to satisfy the fair market value and commercial reasonableness requirements of an applicable exception if the parties relied in good faith on an opinion from a nationally recognized appraisal firm. To prevent opinion shopping, the statute must provide that all opinions (draft or otherwise) of fair market value and commercial reasonableness would be taken into account when determining whether the parties relied in good faith on a favorable opinion. One commenter suggested that such a change should include some standard to govern the amount that can be shared with physicians, such as a cap or threshold.

Expand the Secretary's Authority: Waivers, Exceptions, and Advisory Opinions. Some commenters noted that the Stark law and regulations are payment regulations that providers must comply with to receive payment. An effective regulatory regime requires that the regulated community be able to obtain timely and clear guidance. Commenters offered a number of suggestions in this regard.

Commenters generally agreed that Congress should expand the Secretary's authority to create waivers, exceptions, and advisory opinions. Although some commenters suggested that the authority be limited to expanding waivers for participants in MSSP and other CMMI models, most recommended that the Secretary be given express waiver authority that would apply to innovative payment models under MACRA and other health care reform laws.

The Stark law permits the Secretary to create regulatory exceptions that the Secretary determines do "not pose a risk of program or patient abuse." 42 U.S.C. § 1395nn(b)(4). CMS has taken a cautious approach in issuing Stark exceptions.²⁰ Commenters believe that many of

²⁰ Although CMS recently provided additional guidance on the Stark law, [Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70885](#), 71300-71341 (Nov. 16, 2015), at least one commenter

the existing exceptions are too narrow or complicated to be useful but that more practical exceptions could be issued if the Secretary were given authority to create exceptions where an arrangement does not pose an undue or significant risk of program or patient abuse. Commenters also noted that HHS has greater authority and flexibility to create safe harbors to the AKS, a criminal statute, than it has to create exceptions to the Stark law, a regulation of Medicare payment.

Several commenters also urged Congress to strengthen the Secretary's authority to issue Stark advisory opinions and promote timely agency guidance. One commenter noted that if an exception for innovation arrangements were adopted, it could permit the submission of a request through the CMS advisory opinion process, which would provide added comfort to both CMS and the industry. The commenter noted that Congress could direct CMS to modify its current regulations to accommodate the review process and set forth other requirements CMS considers necessary to organize, facilitate, and fund the analysis and the timely issuance of advisory opinions dealing with innovation arrangements that promote the Triple Aim. This commenter noted that such advisory opinions should not be required, but that they should be available to provide added comfort to the industry in a time of innovation and change.

The participants and commenters agreed that the creation of the Self-Referral Disclosure Protocol (SRDP) and the expansion of the Secretary's authority to compromise Stark repayment obligations were positive developments in Stark law enforcement. Nevertheless, some said the process was too lengthy and left providers in limbo while they waited for a disposition. Many commenters argued Congress should give CMS more discretion to settle Stark law violations, such as providing CMS with the explicit authority to impose CMPs in lieu of compromising repayments based on the total repayment amount.²¹ One commenter suggested Congress give CMS discretion to determine whether to prohibit billing for violations, which could have far-reaching implications, including taking Stark law violations out of the realm of FCA litigation.

Some commenters were not enthusiastic about creating additional waivers or exceptions to the Stark law because they believe that regulatory environment is already overly complex. These commenters also believed it would not be effective to simply strengthen the Secretary's advisory opinion authority to promote timely agency guidance because, based on 25 years' worth of rule-making, they believe Congress should revise the law entirely. In their view, advisory opinions only help at the margins, and, in almost all cases, very slowly.

VI. DEFINING TECHNICAL VIOLATIONS

Commenters generally agreed that "technical" violations should be subject to a separate set of sanctions that would not give rise to either FCA exposure or potentially ruinous repayment

believed that the agency could be more hesitant to issue exclusions after the recent decision in *Council for Urological Interests v. Burwell*, 790 F.3d 212 (D.C. Cir. 2015). This concern underscores the importance of consideration of an explicit grant of authority to the Secretary.

²¹ Recommendations concerning a revised penalty structure are discussed below.

liability.²² Several commenters noted that Congress recognized the disparity between technical and substantive violations when it created the SRDP and authorized the Secretary to reduce amounts owed. In distinguishing technical and substantive violations, comments focused on documentation requirements, adherence to fair market value, the volume or value of referrals, or harm to beneficiaries or federal health care programs. But some commenters questioned whether drawing such a distinction would be helpful because it would be difficult to determine penalty provisions and enforcement priorities in an already hyper-technical environment. Their solution to the complexity would be to eliminate the compensation arrangements prohibition. As for penalties for technical violations, all commenters recommended that CMPs be assessed in lieu of penalties or that no penalty be assessed. Some commenters recommended further reducing the CMP if a party self-disclosed a violation within 60 days of discovery.

Documentation Requirements. Commenters generally agreed that technical violations were those involving the form, not substance, of an arrangement. Commenters and round table participants pointed to Representative Charles Boustany’s proposed legislation, the Stark Administrative Simplification Act of 2015, as a move in the right direction, specifically in terms of its definition of technical violations.²³ The proposed legislation defines “technical noncompliance” as arrangements that violate the law’s prohibition of self-referral “only because (i) the arrangement is not set forth in writing; (ii) the arrangement is not signed by 1 or more parties to the arrangement; or (iii) a prior arrangement expired and services continued without the execution of an amendment to such arrangement or a new arrangement.”²⁴

Several commenters added that technical violations are those that pose a low risk of affecting the Medicare fisc and are unlikely to result in increased use of medically unnecessary services.

Arrangements That Do Not Incentivize Referrals or Unduly Influence Health Care Decision-Making. In describing technical violations, some commenters included along with documentation requirements violations that are irrelevant to whether an arrangement incentivizes referrals. Outside the context of ownership, they only consider “substantive” violations of the Stark law to be compensation structures that induce or reward referrals (*i.e.*, the physician is paid for referrals). Some of these commenters recommended eliminating any technical violations that do not harm patients or Medicare and authorizing the Secretary to impose a CMP for each arrangement to reduce the impact of technical violations. One commenter suggested that a financial arrangement that a reasonable person would conclude creates a significant incentive to a physician to refer to a particular entity is substantive.

Fair Market Value. Some commenters suggested dividing violations into two categories: (1) those where compensation is in excess of fair market value (and perhaps commercial reasonableness) and/or is determined in a manner that takes into account the volume

²² [AHLA 2009 White Paper](#), at 16.

²³ [Stark Administrative Simplification Act of 2015](#), H.R. 776, 114 Cong. (2015).

²⁴ [Stark Administrative Simplification Act of 2015](#), H.R. 776, 114 Cong. (2015).

or value of referrals; and (2) those where compensation is not. However, commenters recognized that the division is not clear cut in practice due to the technical nature of the rules on fair market value and volume or value of referrals. Many commenters and participants agreed that any meaningful change to the Stark law must address volume and value, and, to a lesser extent, fair market value.²⁵ One suggestion was to define technical violations to include any violation that does not involve fair market value (and perhaps commercial reasonableness) or the volume or value prohibition; and that, depending on the facts and circumstances, technical violations may include violations that involve fair market value, commercial reasonableness, or the volume or value prohibition.

Compensation Arrangements That Do Not Violate the AKS. Several commenters recommended defining technical violations as compensation arrangements that do not otherwise violate the AKS. In other words, as suggested above, prohibited ownership violations would be substantive noncompliance, and problematic compensation arrangements would be enforced through the AKS or the CMP law. One commenter suggested that any arrangements that do not confer a financial benefit to the referring physician should not be considered substantive and that technical violations should not carry Stark penalties.

Create Bright Line Requirements For Substantive Noncompliance. One commenter suggested first creating bright line requirements to improve clarity and then considering all noncompliance with those bright line requirements to be substantive. The commenter recommended that Congress direct CMS to specify, on a regular basis (*e.g.*, through Medicare Physician Fee Schedule rule making), compensation practices that are not permitted based on the agency’s experience. Only noncompliance with such specifically non-permitted compensation practices should be viewed as substantive noncompliance. As discussed below, concerns have been raised about Congress’s or CMS’s ability to create a list that would effectively cover all financial arrangements that may involve self-referral concerns.

Clarify Compensation Arrangement Terms. Several commenters recommended clarification of the three key terms in the compensation arrangement exceptions: fair market value (FMV), “takes into account” the “volume or value” of referrals, and commercially reasonable. The comments we heard echoed those raised during the AHLA discussion, including concerns about the difficulty of establishing and documenting FMV.²⁶

Some commenters recommended allowing physician compensation for providing high-quality and efficient care without violating the Stark law’s FMV standard, even if the compensation is related to the volume or value of the referrals. These commenters argue that the statutory definition of FMV simply reflects the clear rule that arrangements must reflect arm’s length bargaining and that the “volume or value” standard was a regulatory addition created by CMS. Another commenter also rejected CMS’ definition of FMV and recommended that Congress clarify that intent is not material in the strict liability law, and bar CMS from defining

²⁵ We received many comments recommending changes to terms associated with compensation arrangement exceptions. They are discussed in Section VI, below.

²⁶ See [AHLA 2009 White Paper](#), at 11-12.

essential terms (*i.e.*, FMV, commercially reasonable and volume or value of referral standards) in a purportedly circular, interconnected manner.

One commenter suggested amending the statute to provide that the FMV requirement is met where the compensation paid to the physician does not exceed FMV. Some commenters noted the confusion caused by the regulations' ambiguity on whether an arrangement that is FMV at its inception, but later falls out of FMV, continues to meet the FMV requirement. Long leases should not enjoy exception for years and short leases should not be punished if the lease falls out of FMV in six months. To address this concern, one commenter suggested that Congress could provide that arrangements that are FMV at their inception are presumed or deemed to be FMV throughout their life, up to some maximum period, such as two to three years. Alternatively, if a party obtains an FMV appraisal from a qualified, independent appraisal firm, it is entitled to rely on the appraisal for the life of the appraisal, up to a maximum of two to three years. A variation would be to specify that, in order to gain the protection of the FMV presumption or deeming, the appraisal be obtained before the arrangement begins. The commenter also recommended a similar provision for an appraisal regarding whether an arrangement is commercially reasonable.

A few commenters sought Congress's explicit confirmation that certain practices are acceptable and do not necessarily violate the Stark law. For instance, one commenter suggested that Congress confirm that DHS entities can base compensation on market surveys of similar arrangements without regard to whether those surveys involve actual or potential referral sources – given that the only available surveys involve entities (*e.g.*, medical practices, hospitals and other employers) and physicians who are in a position to make referrals. The commenter also suggested that the Stark law be amended to clearly state that nothing in the law prohibits a DHS entity from developing and using management, financial, and other reports that may include productivity or other data in their internal operations as consistent with typical business practices, so long as such reports are not used in decision-making regarding the compensation to be paid to individual physicians. Several participants at the round table suggested that Congress remove the “commercially reasonable” requirement from the employment and other compensation exceptions or clarify that operating losses in DHS entity-owned physician practices are not commercially unreasonable.

Others suggested changes to other definitions. One commenter recommended that the definition of “group practice” be revised by removing the current volume or value standard so that physicians who are part of a group practice may be paid on the basis of furnishing care without violating the Stark law. Virtually all of the exceptions to the existing Stark law impose restrictions on compensation based on “volume or value” of referrals; however, inclusion of this language in the group practice definition creates enormous confusion and opportunities for technical non-compliance. Another commenter suggested that the Stark law's definitions of remuneration and compensation arrangement be narrowed so that FMV exchanges do not implicate the Stark law.²⁷

²⁷ See [AHLA 2009 White Paper](#), at 12 (similar suggestion that compensation arrangement prohibitions apply only when payments vary with the volume or value of referrals).

Another commenter suggested Congress amend the Stark law to define reasonable safe harbors that would provide predictable refuge for hospitals that reasonably evaluate and document fair market value.

Intent. While not always tying the suggestion to the definition of technical violations, several commenters recommended that an intent requirement be added such that purely accidental omissions were not in violation of the Stark law. Some participants believed this would make the Stark law duplicative of the AKS rather than a payment rule.²⁸ Others recommended adding a harm to programs requirement to limit fines to situations where the prohibited referrals result in some demonstrable harm to the government or the patients served, with the burden of proof on the government.

Create Exception for Technical Noncompliance. One commenter recommended creating an exception for technical noncompliance based on the regulatory exception for certain arrangements involving temporary noncompliance at 42 C.F.R. § 411.353(f), but with fewer restrictions. The commenter did not specify how to differentiate between technical and substantive violations, but emphasized the importance of such an exception.

Determining the Penalty. Some commenters also advocated for the inclusion of mitigating factors when determining the penalties associated with technical violations, sometimes referring to the factors in the legislation creating the SRDP. Some commenters suggested that Congress give the Secretary explicit authority to reduce penalties or apply CMPs in lieu of penalties, and those commenters also recommended that certain factors be considered with determining the penalty amount. Suggested factors included: (1) whether the violation is technical or substantive; (2) whether the parties' failure to meet all of the prescribed criteria of an applicable exception was due to an innocent or unintentional mistake; (3) the corrective action taken by the parties; (4) whether the services provided were reasonable and medically necessary; (5) whether access to a physician's services was required in an emergency situation; and (6) whether the Medicare program suffered any harm beyond the statutory disallowance. A variation of a suggestion discussed in the previous section would be for Congress give CMS discretion to determine whether to prohibit billing for technical violations, which would allow CMS to compromise repayment amounts, to impose CMPs, or not to impose any penalty.

VII. GENERAL RECOMMENDATIONS BEYOND MACRA IMPLEMENTATION AND DEFINING TECHNICAL VIOLATIONS

Commenters noted general frustrations with Stark law compliance and explained the difficulties hospitals and other providers face in complying with the law. Several commenters noted that even if a provider fits its arrangements squarely within certain exceptions, the provider could still face lengthy and expensive legal battles because many exceptions are fact-specific. For instance, for challenges based on any Stark law exceptions with AKS/Claims Requirements, a hospital would not be able to prevail on a motion to dismiss or a motion for summary judgment because resolving the Stark law claims requires the court to also determine whether the financial relationship at issue satisfies the highly fact-specific AKS/Claims Requirements. As discussed

²⁸ See [AHLA 2009 White Paper](#), at 12 (similar comments on intent).

above, the same is true of each of the three standards (FMV, volume/value, commercial reasonable). The commenters believe that including requirements of separate laws stacks the deck against hospitals trying to obtain predictability with respect to their Stark law compliance. Although the concerns discussed below are not unique to implementing health reform, they create a chilling effect because both hospitals and physicians are wary not only of the difficulties associated with complying with the Stark law but also of the costs associated with defending even compliant arrangements.

Align Stark Law with AKS. As discussed above, many commenters believe Congress should align the Stark law and AKS. Congress (or for regulatory exceptions, HHS) could accomplish this by replacing certain Stark law exceptions with AKS exceptions. For instance, one commenter suggested that the Stark law bona fide employee exception should be made identical to the AKS bona fide employee exception, which unlike the Stark exception does not include a fair market value component. The commenter reasoned that if the concern giving rise to this exception is that part-time employees are more subject to abuse, then the Stark law's fair market value component could be limited to persons who are dually employed by a provider of DHS and a physician practice, but not be applied to physicians whose only employer is a provider of DHS. The commenter also noted that for all tax-exempt entities, there already are substantial constraints on compensation paid to employees. The commenter suggested that any compensation arrangement that satisfies an AKS safe harbor should also be exempt from the Stark law. Rather than maintaining two parallel, but not identical, sets of regulations that outline permitted practices, the commenter believes it would be better to rely on the AKS safe harbors and eliminate the separate, but not identical, exceptions to the compensation arrangements provisions of the Stark law.

Tax Exempt Exception for Compensation Arrangements. One commenter noted that the Internal Revenue Service (IRS) already limits compensation arrangements entered into by tax exempt entities, and that in light of such limitations, a potential carve out to the Stark law could be an exception applicable to any compensation arrangement that is entered into by a tax exempt enterprise. That commenter suggested that clearer, broader exceptions for bona fide co-management arrangements, professional courtesy, reasonable gifts or rewards for patient referrals, and free screenings would be helpful.

Reverse the Premise and Change the Burden of Proof. One commenter recommended reversing the premise of the Stark law to specify types of particular compensation arrangements that are "strict liability" and place the burden on government to show a violation. The commenter also recommended that penalties be made commensurate with the harm to the Medicare program. Although the structure of the Stark law has long been debated, the main argument against reversing the premise is the difficulty in defining a list of all illegal arrangements that could mask self-referrals.²⁹

Simplify/Clarify. Many of the participants suggested that the Stark law's definitions and exceptions should be streamlined and simplified. Some commenters suggested eliminating or modifying the signature requirement. One commenter recommended removing the limitation on

²⁹ See [AHLA 2009 White Paper](#), at 13.

the number of times a hospital may use the late signature rule, or in the alternative, modifying the signature requirement to simply require evidence of assent between the parties.

Other commenters recommended that the Stark law should be amended to codify CMS policy confirming that payments to physicians for personally performed services are permissible under the Stark law, even if the personally performed services are related to DHS ordered by the physician. These commenters suggest an amendment identifying the following as permissible forms of payment for personally performed services: (1) hours worked in performing such services; (2) revenues billed, collected or collectible for such services; (3) wRVUs for such services; (4) patient encounters; (5) average daily patient census; or (6) any other approach that measures the clinical or administrative services actually furnished by the physician. For every physician (whether or not in a group practice), services that are billable as “incident to” the physician’s services are deemed to be personally performed by the physician.

VIII. CONCLUSION

The Stark law was created to address a risk in an FFS payment model. The financial incentives that trigger overutilization concerns in an FFS payment model are largely or entirely eliminated in alternative payment models. Although the FFS payment model still exists, the comments show that the Stark law and its regulations have presented challenges to providers attempting to implement health care reform. Many commenters cited the Stark law’s strict liability standard and significant penalties as serious obstacles to implementing MACRA and other alternative payment reforms. The Committee appreciates all of the comments submitted and will be considering them all as we evaluate and develop potential changes to the Stark law.

Greer, Leslie

From: Fernandes, David
Sent: Thursday, December 08, 2016 2:35 PM
To: Glenn F. Elia; 'klg1@aol.com'
Cc: Riggott, Kaila; Greer, Leslie
Subject: 2nd Completeness Letter for CON 16-32117
Attachments: 16-32117-Completeness Letter 2 Final.docx

Good afternoon Mr. Elia and Ms. Gerner,

Please see the attached completeness letter in the matter of the proposed acquisition of a mobile 1.5T MRI. In responding to the completeness letter, please follow the instructions included in the letter and provide the response document as an attachment only (no hard copies required). Please provide your written responses to OHCA by February 6, 2017.

Email to OHCA@ct.gov and cc: David.Fernandes@ct.gov and Kaila.Riggott@ct.gov.

If you have any questions regarding the completeness letters, please contact David Fernandes at (860) 418-7032.

Please confirm receipt of this email.

Thank You,

David Fernandes

Planning Analyst (CCT)
Office of Health Care Access
Connecticut Department of Public Health
410 Capitol Avenue, Hartford, Connecticut 06134
P: (860) 418-7032 | F: (860) 418-7053 | E: David.Fernandes@ct.gov



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH



Raul Pino, M.D., M.P.H.
Acting Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

December 8, 2016

VIA EMAIL ONLY

Mr. Glenn F. Elia
Chief Executive Officer
Connecticut Orthopedic Specialists, P.C.
2408 Whitney Avenue
Hamden, CT 06518

Ms. Patricia A. Gerner
Principal
The Law Office of Patricia A. Gerner, LLC
240 Ramstein Road
New Hartford, CT 06057

RE: Certificate of Need Application; Docket Number: 16-32117-CON
Acquisition of a Mobile 1.5T Magnetic Resonance Imaging Scanner
Completeness Letter

Dear Mr. Elia and Ms. Gerner:

On November 8, 2016, OHCA received responses to the first completeness letter in the above referenced matter. OHCA requests additional information pursuant to Connecticut General Statutes §19a-639a(c). Please electronically confirm receipt of this email as soon as you receive it. Provide responses to the questions below in both a Word document and PDF format as an attachment to a responding email. **Please email your responses to all of the following email addresses: OHCA@ct.gov, David.Fernandes@ct.gov and Kaila.Riggott@ct.gov.**

Pursuant to Section 19a-639a(c) of the Connecticut General Statutes, you must submit your response to this request for additional information no later than sixty days after the date that this request was transmitted. Therefore, please provide your written responses to OHCA no later than **February 6, 2017**, otherwise your application will be automatically considered withdrawn.

Paginate and date your response (i.e., each page in its entirety). Repeat each OHCA question before providing your response. Information filed after the initial CON application submission



Phone: (860) 509-8000 • Fax: (860) 509-7184 • VP: (860) 899-1611
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
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(e.g., completeness response letter, prefiled testimony, late file submissions, etc.) must be numbered sequentially from the Applicant’s preceding document. Begin your submission using **Page 249** and reference “**Docket Number: 16-32117-CON.**”

1. Why were the majority of COS referrals made to Shoreline Medical Center, (e.g., proximity, joint agreement, etc.)?
2. Please clarify what is meant by “currently *almost all* of the patients from the Shoreline Orthopedics and Sports Medicine offices of COS and many of the patients from the 6 COS offices in Orange, Milford and Shelton are referred to *non-COS providers* for MRI scans,” as found on page 221. Also, please reconcile this statement with the table below, created using information on pages 26-27 of the application, which appears to indicate the majority of patients were referred to another COS facility. Please explain any corrections.

	Patients Referred to Non-COS Facility	Patients Referred to a COS Facility
Essex Service Area	563	950
Orange Service Area	447	1,041

3. How will MRI results from the mobile MRI be conveyed to Dr. Gagliardi?
4. Please update Table 5 on page 42 with year-to-date volume for the most recently completed fiscal year and explain any increases or decreases.
5. Based on the Applicant’s assumption of operating 75 hours a week and at 45 minutes per scan as indicated on page 34, what is the maximum number of scans and number of patients that COS can currently accommodate at each location?

If you have any questions concerning this letter, please feel free to contact me at (860) 418-7032, or Kaila Riggott at (860) 418-7037.

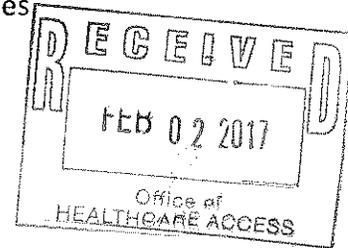
Sincerely,

David Fernandes
Planning Analyst (CCT)

User, OHCA

From: Glenn F. Elia <gelia@ct-ortho.com>
Sent: Thursday, February 02, 2017 12:03 PM
To: User, OHCA; Fernandes, David; Riggott, Kaila
Cc: 'klg1@aol.com'
Subject: OHCA Docket No. 16-32117- CON 2nd Completeness Responses from COS
Attachments: Exhibit List R2.docx; COS Completeness #2 1.26.17.pdf; COS Completeness #2 1.26.17.docx; Exhibit List R2.pdf

From: Glenn F. Elia gelia@ct-ortho.com
To: OHCA@ct.gov., David.Fernandes@ct.gov. kaila.riggott@ct.gov, klg1@aol.com
Subject: OHCA Docket No. 16-32117- CON 2nd Completeness Responses to OHCA Questions dated December 8, 2016.
Date: February 2, 2017



Dear Ms. Riggott and Mr. Fernandes,

Attached please find the Word version of the COS Responses to OHCA's Completeness Questions dated December 8, 2016, which includes four (4) new exhibits. A copy of the same Completeness Responses, with four (4) Exhibits is also attached in pdf format. The Revised Exhibit List is attached in both word and pdf format.

Please let me know if you need anything further. I would also appreciate knowing that you have received this email transmission with the four attached files. Thank you for your assistance.

Best regards,

Glenn Elia, CEO
Connecticut Orthopaedic Specialists, P.C.

Exhibit List

Exhibit	Description	Pages
A	Map of COS Locations; List of COS Office Addresses; and List of All COS Physicians.	59 - 68
B	Graphs of Increased MRI Scanning in Hamden and Branford FY 2013 - 2016.	69 - 72
C	DPH License for Outpatient Surgery Center in Branford.	73 - 74
D	List of Key Professional, Administrative, Clinical and Direct Service Personnel and Curriculum Vitae.	75 - 91
E	Scholarly Articles.	92 - 122
F	Letters of Support.	123 - 130
G	COS Standard of Practice Guidelines.	131 171
H	American College of Radiology Accreditation for Existing MRI Scanners.	172 - 174
I	COS Charity Care Policy.	175 - 176
J	Target Populations: Patient Zip Codes.	177 - 193
K	FY2015MRI Scans in the Essex Area for COS Patients.	194 - 196
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M	Capital Expenditures for Mobile MRI and Quotation for Trailer Installations.	199 - 203
N	Funding or Financial Resources for the Project	204 - 208

O	COS Financial Statements; Balance Sheets and Related Income Statements for FY 2014 and 2015.	209 - 213
P	Financial Worksheet.	214 - 215
Q	Assumptions Used in Financial Worksheet.	216 - 218
R	Senate Finance Committee Majority Staff Report, 'Why Stark, Why Now?'	228-248
	COS Completeness Responses #2 dated February 2, 2017	249 - 256
S	COS Disclosure Form used in the COS offices within the Shoreline Orthopedic & Sports Medicine practice disclosing other locations for a MRI scan in the geographic area.	257 258
T	Payer Mix for COS for FY2016.	259 - 260
U	Ohsfeldt, Robert L, Pengxiang, Li and Schneider, John E, <u>Health Economics Review</u> "In-Office Magnetic Resonance Imaging (MRI) Equipment Ownership and MRI Volume Among Medicare Patients in Orthopedic Practices", 2015.	261 - 271
V	2016 MRI Non-Operating Hours for the Hamden and Branford MRIs.	272 -274

**CON Application: OHCA Docket Number 16-32117-CON
Connecticut Orthopaedic Specialists, P.C.
Acquisition of a Mobile 1.5T MRI Scanner
Completeness Responses #2: February 2, 2017**

□

1. Why were the majority of COS referrals made to Shoreline Medical Center, (e.g., proximity, joint agreement, etc.)?

Response: There is a list available to COS patients who are patients of the Shoreline Orthopedics & Sports Medicine practice as to where the patient can have the required MRI scan performed. The patients decide where to go. (*See Exhibit S*). Patients are not referred to a specific facility. It is assumed that proximity was the reason patients chose the Shoreline Medical Center rather than other facilities which are at a greater distance. There is not now, nor has there ever been, a joint agreement between Shoreline Orthopedics & Sports Medicine and the Shoreline Medical Center.

2. Please clarify what is meant by “currently *almost all* of the patients from the Shoreline Orthopedics and Sports Medicine offices of COS and many of the patients from the 6 COS offices in Orange, Milford and Shelton are referred to *non-COS providers* for MRI scans,” as found on page 221. Also, please reconcile this statement with the table below, created using information on pages 26-27 of the application, which appears to indicate the majority of patients were referred to another COS facility. Please explain any corrections.

	Patients Referred to Non-COS Facility	Patients Referred to a COS Facility
Essex Service Area	563	950
Orange Service Area	447	1,041

Response: The information found on p. 221 is specific to the Shoreline Orthopedic & Sports Medicine offices only, whereas the above table refers to the “Essex Service Area”. It does not include patients who live in the Essex service area who were treated at another COS facility and had a MRI scan at a COS facility. Virtually all of the patients from the Shoreline Orthopedic & Sports

Medicine practice (which does not include all COS patients in the Essex service area) went to a non-COS facility for their MRI scan because of the lack of existing MRI capacity at both of the existing COS MRIs in Hamden and Branford. The total number of Shoreline Orthopedics & Sports Medicine patients who had the MRI scan done at a non-COS facility was 963 (569 of this number are residents of the Essex service area and another 394 patients came from outside of the Essex service area.).

But an additional 950 patients who live in the Essex service area, and were treated by an orthopedic physician in a COS office other than Shoreline Orthopedics & Sports Medicine in 2015 were referred to a COS facility for their needed MRI (COS in Branford or Hamden). Therefore, approximately the same number of patients in the Essex service area use COS for their MRI scanning (950) as the total number seen at Shoreline Orthopedics & Sports Medicine who have to go to another facility (963). (See CON App., Exhibit J1, p.181 and supporting statistics on pp. 178-180, and Exhibit K, pp. 194-196).

The majority of the patients who see COS physicians in the 6 COS offices in Orange, Milford and Shelton utilize the COS scanners in Branford and Hamden for their MRI scans. The information found on pp. 26-27 of the CON application refers to both the Orange and Essex service areas. The majority of the COS patients in the Orange area use one of the two existing COS MRIs for MRIs scanning.

The Essex service area is very different than the Orange service area.

Essex:

The statement that almost all of the patients from COS Shoreline Orthopedics & Sports Medicine were sent to a non-COS facility for the MRI scan is accurate. In 2015, of the 963 COS Shoreline Orthopedics & Sports Medicine patients who had a MRI scan at a non-COS facility, 569 of them reside in the Essex service area. (See pp. 26-27 of the CON application.) Another 394 patients came from outside of the Essex service area to be treated at the one of the COS Shoreline Orthopedics & Sports Medicine offices. Therefore, the number of patients referred to a non-COS facility in the chart should be 569, but only from the 3 Shoreline Orthopedic & Sports Medicine offices. (See chart below). As stated above, almost all patients from the Shoreline Orthopedics & Sports Medicine offices (residents and non-residents of the Essex service area) had to go to a non-COS facility for the MRI scan, because there is no MRI scanner available at any of the Shoreline Orthopedics & Sports Medicine offices, the two COS MRI scanners in Branford and Hamden are a long distance from Essex, and the two COS scanners have no additional capacity to accommodate the Shoreline Orthopedic & Sports Medicine patients.

Essex Service Area

	Patients Referred to a Non-Cos Facility	Patients Referred to a COS Facility
COS patients living in the Essex Service Area treated by Shoreline Orthopedic & Sports Medicine	569	0
COS patients living outside the Essex Service Area treated by Shoreline Orthopedic & Sports Medicine	394	0
Patients living in the Essex Service Area treated by COS (other than the Shoreline Orthopedic & Sports Medicine practice).	0	950
Totals in Essex Service Area	569 *	
Total of Shoreline Orthopedic & Sports Medicine Referrals	963	

*Correction: The number 563 in the chart included in Question #1 as the number of patients in the Essex service area treated by physicians of the Shoreline Orthopedics & Sports Medicine practice should have been 569. This was a typographical error (See CON application, page 26).

As noted above, 950 patients who live in the Essex service area, are being seen by a physician at a COS office other than one of the Shoreline Orthopedics & Sports Medicine offices. These are the patients who currently have MRI scanning done at the either of the two existing COS MRI scanners in Hamden or Branford. It is anticipated that a majority of the 950 patients who have used

the COS MRI in Hamden or Branford, but live in the Essex service area, will use the mobile MRI in Essex, if it is approved. Having the mobile MRI within the physician practice in Essex should be much more accessible for these patients than Branford or Orange. This shift will reduce the number of scans done at the COS offices in Hamden and Branford, freeing up extra capacity for those patients who live closer to those two offices.

Orange

The statement on page 221 of the CON application that is specific to the Orange, Milford and Shelton COS offices is accurate that “many of the patients from the 6 COS offices in Orange, Milford and Shelton” were referred to non-COS providers for MRI scans in 2015. This happened due to the addition of 3 new COS offices in the Orange service area in the last few years, in addition to the three existing COS offices in the area (1 in Milford, 1 in Orange, and one in Shelton). COS has run out of capacity on both its MRI scanners and has had to refer patients to other providers. However, most of the COS patients from the 6 COS offices in the Orange service area used the existing COS MRI in either Hamden or Branford.

Orange Service Area

	Patients Referred to a Non-COS Facility	Patients Referred to a COS Facility
COS Patients living in the Orange Service Area	447	1,041

In 2015, 1,041 patients seeing a COS physician at one of the six offices in the Orange service area were referred to the COS MRI either in Hamden or Branford. Only 447 patients received a MRI study at a non-COS facility. Therefore, it is accurate to state that the majority of COS patients (1,041) in the Orange service area have their MRI scan done at a COS facility (Branford or Hamden), while the minority (447) had to have their MRI scan done at a non-COS facility. For those patients who prefer to choose to have a MRI scan done at a COS facility, it is expected than many patients who would have traveled to Branford or Hamden will choose to use the proposed mobile MRI at the COS office in Orange, if it is approved.

3. How will MRI results from the mobile MRI be conveyed to Dr. Gagliardi?

Response:

COS uses Greenway Prime Suite as our Electronic Medical Records (“EMR”) provider. Greenway uses an order-based interface with our PACS system, Ambra Healthcare. Ambra is a cloud based PACS upon which all of the COS MRI studies are directly uploaded and stored via a secure interface. The COS radiologist, Dr. Gagliardi, is able to log into the COS web portal with a secure log-in and view all MRI studies for his review. His report is loaded directly back into the COS EMR, Greenway, under the patient account. This happens within 24 hours of the MRI study being performed. Treating physicians can access the MRI study by logging into the COS / Ambra portal, just like the radiologist. The report from the radiologist is likewise available to the treating physician both from the clinic and remotely by logging into the secure portal for treating physicians. Patients who wish to access their MRI study can do so by requesting that COS give them a secure log-in to a patient portal in the Ambra website. Patients can only access their own study. This access is provided by COS only upon the request of the COS patient.

4. Please update Table 5 on page 42 with year-to-date volume for the most recently completed fiscal year and explain any increases or decreases.

Response:

Table 5 has been updated to include actual data for FY 2016. The volume on the COS Branford MRI increased by 847 scans (from 3,851 in FY 2015 to 4,698 in FY2016), which was an increase of 20%. *See* CON App., Table 5, p. 42. The volume at the COS Hamden MRI increased from 3,773 scans in FY2015 to 4,410 scans in FY2016, an increase of 637 scans. This amounts to a 17% increase in volume. COS increased the number of scans at both Branford and Hamden from a combined total of 7,624 scans in FY2015 to 9,108 scans in FY2016.

COS traditionally had a 3% increase in MRI scans per year prior to the addition of the new practices which joined COS between 2014 and 2015. *See* CON App., Table 5, p. 42. The numbers increased dramatically after the new offices joined COS, but have now leveled off. However, new patients are continuing to seek medical help at COS offices, as evidenced by the growth over the last year. Instead of hoping for additional patients (or additional physicians) in the future to utilize a new MRI, COS already has the patients who are ready to begin using the proposed mobile scanner in Orange and Essex.

**TABLE 5
HISTORICAL UTILIZATION BY SERVICE
MRI Scans**

MRI Service	Actual Volume (Last 5 Completed FYs)				
	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Connecticut Orthopaedic Specialists 84 North Main Street Branford, CT (MRI)	2,886	2,095	2,577	3,851	4,698
Connecticut Orthopaedic Specialists 2416 Whitney Ave Hamden, CT (MRI)	2,214	3,141	3,725	3,773	4,410
Total	5,100	5,236	6,302	7,624	9,108

In addition to updating the utilization for the most recently completed fiscal year, COS examined the payer mix for COS services for the same time period.

COS became a Medicaid provider in 1977. However, St. Raphael's Hospital absorbed most of these patients in the Hamden/New Haven area. It has only been since the closure of St. Raphael's that COS has seen an influx of Medicaid patients. This began in 2014 with a very few patients, and has grown each year since St. Raphael's closed. While the payer mix showed only a .7% Medicaid use of COS MRI scanners in FY 2015 and the first 6 months of 2016 (See CON App. Table 7, p. 42), that volume increased in FY2016 to .86%. (See Exhibit T). Also, for all COS practices in FY 2016,, the volume of Medicare patients seen in general (not a count of MRI scans) was 28% (excluding Shoreline Orthopedic & Sports Medicine, "Shoreline"). The Shoreline payer mix in FY2016 was 5.2% for Medicaid patients and 18.7 % Medicare patients. (See Exhibit T.)

COS believes that it will fully utilize the mobile MRI four days a week within the next 3 years. The Medicaid population is expected to increase as part of the 3% increase in volume COS has projected over the next 3 years because COS had been experiencing a 3% increase in volume in the years prior to the addition of the new physician practices that joined COS in 2014 and 2015. See CON App., Table 6, p. 43. And the increase in MRI volume on the existing COS scanners in Branford and Hamden in the last year also easily supports 3% growth per year See Table 5 above.

In-office MRI scanning is allowed under the federal Stark law. There is evidence that physicians who have in-office MRI scanning have not been found to order more MRI scans than if they sent the patient to a radiologist's office or another facility for the MRI scan. Health Economics Review produced a study entitled "In-office Magnetic Resonance Imaging (MRI) Equipment Ownership and MRI Volume Among Medicare Patients in Orthopedic Practices" (Exhibit U) which used Medicare data that substantiated the fact that orthopedic physician practices acquiring on-site MRI scanners did not significantly increase the volume of MRI scans performed once the MRI was owned by the physician practice.

The authors in this study compared orthopedic practices without MRI capability with other orthopedic practices which acquired a MRI after having been in practice at least one full year without MRI capacity in-house. Three years of Medicare Part B utilization data were obtained for 2007, 2008 and 2009 from the physician practices which had acquired in-office MRI, and those orthopedic physician practices with no in-house scanning who referred their patients to other providers for a MRI scan. By analyzing the data of the physicians during the year prior to acquiring an in-office MRI, the authors found that "the physicians in practices acquiring onsite MRI capacity had higher MRI volume before MRI acquisition than physicians in similar practices that did not subsequently acquire onsite MRI capacity." (Exhibit U, p. 8).

The article stated that, "None of our model results suggest any substantive change in Medicare MRI volume one-year post on-site MRI-acquisition and one-year pre-onsite MRI acquisition for physicians in MRI-acquiring practices relative to physicians in the non-MRI comparison practices. This finding is inconsistent with results reported in much of the literature focused on the issue of "self-referral" for imaging services. (Exhibit U, p. 8.)

The article concluded that:

"In all of the Medicare MRI volume change models estimated, the estimated impact of onsite MRI acquisition on the change in Medicare MRI volume is consistently small and not statistically significant. Thus, our data analysis provides no empirical support for the proposition that acquisition of onsite MRI capacity within an orthopedic surgery practice induces an increase in the rate of MRI use for Medicare patients among practice providers, relative to physicians in practices without MRI capacity over the same time period."
(Exhibit U, p.12)

- 5. Based on the Applicant's assumption of operating 75 hours a week and at 45 minutes per scan as indicated on page 34, what is the maximum number of scans and number of patients that COS can currently accommodate at each location?**

Response:

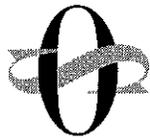
Each of the MRI scanners currently are in operation 13 hours per day Monday through Friday and 10 hours on Saturday, for a total of 75 hours per week. The average MRI scan takes 45 minutes, which results in a total of 98 scans per week (17 scans per weekday and 13 scans on Saturday). The scanners are closed for 8 holidays (New Year's Day, Good Friday, Memorial Day, July 4, Labor Day, Thanksgiving and the day after, and Christmas) which results in a reduction of 136 scans (17 scans x 8 days). This results in a maximum of 4,960 scans annually.

The COS scanner in Hamden was out of operation 18.5 hours in 2016 due to machine maintenance, 14 hours due to weather cancellation and 4.5 hours due to ACR testing. The COS scanner in Branford was closed 44 hours for machine maintenance, 14 hours for weather cancellation and 4.5 hours for ACR testing and 10.5 hours for air conditioning repair. (See Exhibit V). These factors vary by year and were not included in the calculation of maximum number of scans, but such factors have an impact on the number of scans that could be performed.

In 2016 4,698 MRI scans were performed in Branford which results in a 94.7% utilization rate based on 4,960 scan annual capacity. During the same period 4,410 scans were performed in Hamden which results in an 88.9% utilization rate based on a 4,960 scan annual capacity.

General Note: The COS Shoreline Orthopedics & Sports Medicine practice closed its office in Guilford after the CON application was submitted. All COS Shoreline Orthopedics & Sports Medicine patients are now seen by the same physicians either in the Shoreline Orthopedics & Sports Medicine facility in Essex or in Madison. There has been no change in the number of physicians in the Shoreline Orthopedics & Sports Medicine practice, and the specific physicians remain the same as listed in Exhibit A of the CON application.

EXHIBIT S



Connecticut Orthopaedic Specialists

THE EXPERIENCE MATTERS

Diagnostic Imaging Disclosure Statement

Connecticut Orthopaedic Specialists provides advanced imaging services such as MRI for patient convenience. New regulations within the Affordable Care Act, however, require physicians to notify patients of alternate MRI locations within their area. You may have your MRI done at COS or any of the following locations:

<i>Location</i>	<i>MRI Phone</i>	<i>MRI Fax</i>
Middlesex Hospital dba Shoreline Medical Center	(860) 358-2600	(860) 358-2626
Middlesex Hospital Outpatient Center	(860) 358-2600	(860) 358-2626
Middlesex Hospital	(860) 358-2600	(860) 358-2626
Open MRI of Middletown	(860) 346-7400	(860) 347-7900
Guilford Radiology	(203) 453-5123	(203) 458-0427
Groton MRI	(860) 448-6736	(860) 448-6215
Connecticut Orthopaedic Spec. (Branford)	(203) 407-3500	
Connecticut Orthopaedic Spec. (Hamden)	(203) 407-3500	

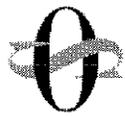
We are also required to obtain your signature as acknowledgement that you have received this form.

Patient Printed Name: _____

Patient Signature: _____

Date: _____

EXHIBIT T



Connecticut Orthopaedic Specialists

AND OUR DIVISIONS

The Orthopaedic Group

OrthopedicHealth



Center For Orthopaedics



SHORELINE ORTHOPEDICS & SPORTS MEDICINE

The payer mix numbers for Medicare and Medicaid that reflect COS and Shoreline as a whole for FY2016 are as follows:

COS Practice

(payer mix percentage of new patients in 2016)

	% of Patients
Medicare	28%
Medicaid	2%

Shoreline Practice

(payer mix percentage of new patients in 2016)

	% of Patients
Medicare	18.7%
Medicaid	5.2%

COS MRI units *(payer mix percentage of MRI scans)*

	% of Patients
Medicare	21.345%
Medicaid	0.86%

EXHIBIT U

RESEARCH

Open Access



In-office magnetic resonance imaging (MRI) equipment ownership and MRI volume among medicare patients in orthopedic practices

Robert L. Ohsfeldt^{1*}, Pengxiang Li² and John E. Schneider³

Abstract

Background: Concerns have been raised about physician ownership of onsite advanced imaging equipment as allowed under Stark laws by the in-office ancillary service exception (IOASE).

Methods: A web-based survey of orthopedic practices in the United States was used to assign a first date of onsite MRI capacity acquisition (if any) to specific orthopedic practices. Medicare claims data for 2006–2010 was obtained for providers in orthopedic practices acquiring onsite MRI capacity and in matched orthopedic practices without an onsite MRI over the same period of time. Multivariate regression was used to estimate the change in provider Medicare MRI volume one year before and one year after the onsite MRI acquisition year for providers in MRI practices compared to providers in propensity-score matched non-MRI practices.

Results: In all of the MRI volume change models estimated, the association between onsite MRI acquisition and the change in provider Medicare MRI volume (one-year post-onsite-MRI-acquisition less one-year pre-acquisition) was consistently small and not statistically significant. This lack of association was robust to changes in model specification in terms of types of MRI exams considered, specific covariates included in the multivariate model, or the process used to confirm individual provider affiliation with study practices in study years.

Conclusions: Our analysis of Medicare claims data provides no empirical support for the proposition that acquisition of onsite MRI capacity within an orthopedic surgery practice induces an increase in the rate of MRI use for Medicare patients among practice providers, relative to physicians in practices without MRI capacity over the same time period.

Keywords: Medicare; Physician self-referral; Orthopedic practice; Transactions costs

Background

Considerable concern has been expressed about the effects of physician ownership of imaging equipment on the use of such services in the United States [1–4]. A series of laws known as “Stark Laws” (named for the law’s primary sponsor, United States Congressman Pete Stark) generally prohibit physicians from referring patients covered by Medicare (a universal public insurance program for persons age 65 or older) for certain “designated health services” if the referring physician or his/her family has a financial relationship with the service provider. The first

of these laws (“Stark I”), effective in 1992, banned referral of Medicare patients to provider-owned clinical laboratories. Effective in 1998, “Stark II” expanded the self-referral ban to a number of additional ancillary health services, and extended the self-referral ban to patients covered by Medicaid (a public insurance program for low income individuals). Finally, effective in 2007, “Stark III” provided additional regulatory guidance for compliance, such as defining specific provider compensation arrangements as analogous to ownership interests [5, 6].

The Stark Law restrictions on physician self-referral were intended to avoid the financial incentives for physicians to increase the volume of referrals for ancillary services, particularly with physician ownership of imaging service capacity [7–17]. However, many factors affect

* Correspondence: rohsfeldt@tamu.edu

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decisions about which patients receive imaging services. Carey and Garrett found that the use of CT and MRI exams for low back pain patients was associated with patient characteristics, such as baseline functional status [18]. In a randomized controlled trial of patients with low back pain, Gilbert and colleagues found those who received "early" imaging had better outcomes than those receiving delayed imaging [19]. If onsite imaging advances the timing of imaging or otherwise enhances the appropriate use of imaging in treatment, onsite imaging may improve the quality of care. Some have questioned whether the lower rate of referral among physicians without ready access to imaging capacity represents underuse rather than overuse by physicians with such capacity [20]. Indeed, the rationale for the "In-Office Ancillary Services Exception" (IOASE) to the Stark restriction relates to the potential benefits of onsite ancillary service availability [5].

The incentives for physician practices to acquire onsite imaging capacity extend beyond the indirect payment from a referral to a physician-owned service in a fee-for-service (FFS) payment system. The relationship between a physician practice and ancillary services represents a "vertical relationship," which can be organized through market-based contractual arrangements or through vertical integration [21, 22], i.e., direct practice ownership as permitted by IOASE. Orthopedic practices without an onsite MRI typically refer patients to a shared MRI facility, often offered through a hospital outpatient department (HOPD) proximate to the practice location, but practices relying on shared facilities have less control over the scheduling of MRI exams.

Thus, the choice of using onsite or shared MRI equipment is a variant of the classic "make or buy" decision in organizational economics, which is mainly influenced by scope economies and transaction economies [23–29]. The make-or-buy decision has been studied extensively in the context of transaction cost economics, which posits that the boundaries of organizations are in large part a function of the nature of the business transacted, where relatively complex transactions are more efficiently organized in settings that feature stronger administrative controls, such as ownership [23, 27, 29]. In the market for medical care, consumer transaction costs are the costs incurred to the consumer to complete a transaction, including the time necessary to implement informed choice, such as evaluating, choosing and locating a care provider, as well as the time spent directly obtaining the services [22]. Consumer transaction costs are expected to be lower in the case of onsite MRI availability because patients may be able to economize on identifying, vetting, locating and traveling to a provider [30]. In addition, there are several potential convenience-related benefits associated with onsite availability, including

easier scheduling, enhanced adherence to treatment plans [31, 32], and "one-stop shopping" [33–35]. Likewise, monitoring costs may be reduced via onsite MRI capacity, to the extent it permits practices to improve supervision of the quality of care, and allows for better coordination among patients, physicians, and ancillary services, and to provide incentives for patients to adhere to recommended treatment plans [36].

Opponents of IOASE contend that the purported benefits of onsite availability are non-existent or overstated [37], instead focusing on the role of asymmetrical and imperfect information, which may allow providers to "induce" demand for ancillary services [8–17]. The potential impact on the extent of demand inducement resulting from physician ownership of imaging services under FFS payment relates to the magnitude of the indirect payment to providers from imaging service ownership, which would be analogous to an equivalent increase in the direct provider payment for professional services [22]. The impact of this incentive is muted by payer policy which often requires pre-authorization or pre-certifications, thus limiting provider discretion over the provision of imaging services [38, 39].

Those advocating an end to IOASE point to a number of studies concluding the financial incentives from physician self-referral causes an increase in the volume of services provided under FFS payment so large as to outweigh any benefits [8–17], though some suggest that movement away from FFS payment would be a superior solution compared to ending IOASE [40]. However, most of these studies do not provide adequate adjustment for incentives beyond self-referral for practices to acquire onsite services, which is a likely source of bias toward finding a positive association between MRI acquisition and MRI volume.

The present study addresses this methodological limitation in the existing literature by using Medicare claims data to assess the extent of differences in MRI exams for Medicare patients among providers in orthopedic practices before and after their practice acquired onsite MRI capacity, compared to physicians in matched orthopedic practices without onsite MRI over the same period of time.

Methods

A persistent challenge in the literature on this subject is the limited data on the extent and timing of physician practice acquisition of imaging capacity. The present study used a web-based survey of orthopedic practices in the United States to determine the date of onsite MRI capacity acquisition, or the absence of onsite MRI capacity, to facilitate a comparison of MRI use with/without onsite MRI capacity. A practice-level propensity score (PS) matching approach was used to match orthopedic

practices with onsite MRI to non-MRI practices. Multivariate regression models were used to examine the change in Medicare MRIs per Medicare patient one year before and one year after the onsite MRI acquisition year for providers in MRI practices compared to providers in non-MRI comparison practices.

Practice survey data

A survey of orthopedic practices in the United States was initiated in July 2012 with the support of the American Academy of Orthopaedic Surgeons (AAOS) to determine the date of first acquisition onsite MRI equipment (if any), and general information about the practice. Details about the administration of the AAOS practice survey have been reported elsewhere [41].

For practices reporting onsite MRI capacity, respondents were asked to report the number of practice providers (and their UPIN/NPI numbers) authorized to order an MRI as of the year of their first onsite MRI acquisition. All non-MRI practice respondents reported the number of current providers in the practice authorized to order MRI exams (and their UPIN/NPI numbers).

By September 2012, the orthopedic practice survey was closed with a total of 770 responses received. Eliminating duplicate and incomplete responses yielded 740 practice responses. An additional 185 practices did not report provider ID numbers (167 [90 %] of these reported no onsite MRI capacity) and thus were excluded from the practice sample used for PS matching of onsite MRI and comparison non-MRI practices.

Selection of MRI and non-MRI practices

At the time of this study, the most recent full year of Medicare claims data available was for 2010. To assure a full year of Medicare claims data before and after MRI acquisition, 63 practices which reported a first MRI acquisition in 2007, 2008, or 2009 were classified as MRI "case" practices. Similarly, 465 practices without an onsite MRI by December 31, 2010, or practices which acquired an onsite MRI after January 1, 2011, were classified as non-MRI practices.

Preliminary confirmation of the respondent-reported physician ID numbers was obtained by using the survey-reported physician ID numbers to the NPI/UPIN crosswalk file to get a UPIN number (for physicians with an NPI in the survey) or NPI number (for physicians with a UPIN in the survey). Next, we merged the survey physician UPIN/NPI numbers with the CMS National Plan and Provider Enumeration System (NPPES) Full Replacement Monthly NPI File [42] for the MRI acquisition year (for MRI practices) or 2012 (for non-MRI practices).

Comparing the city and state of the provider's business mailing address from NPPES to the survey reported city

and state of practice address revealed the states did not match for more than 50 % of the physician ID numbers for 195 of the survey practices. These 14 MRI practices and 181 non-MRI practices were excluded from the practices considered for inclusion in the final sample of practices (see Table 1). In addition, we excluded 172 practices not serving Medicare beneficiaries and all providers without valid UPIN/NPI.

For the resulting sample of 32 MRI practices and 129 non-MRI practices, we used a propensity score (PS) approach to identify specific non-MRI (comparison) practices to be matched to specific MRI (case) practices. The PS matching approach was originally developed in part to enhance the efficiency of sampling comparison observations to be included in the study sample over random sampling from a large pool of potential observations [43]. The first step in the PS matching approach is to estimate a model to predict the likelihood of onsite MRI acquisition for individual practices based on various practice characteristics – specifically practice characteristics that might also affect the volume of MRI exams performed by practice providers.

We used a logistic regression model predicting the likelihood of onsite MRI acquisition which included as predictor variables the number of providers in the practice, practice payer mix (Medicare revenue share), number of Medicare beneficiaries they served, number of providers with valid UPIN or NPI, percentage of providers in the same city during our study years, and dummy variables for Census region (model results not reported). The Hosmer–Lemeshow χ^2 test statistic for the model is 21.8 ($p < 0.01$), with a c-statistic of 0.827 and McFadden's R-squared of 0.30. The common support for the PS model (in terms of predicted probabilities) covers the range of 0.056 to 0.921, with 76 % of practices (123 out of 161) in this range. Only the practice size variables (number of providers in the practice, number of Medicare beneficiaries served, and number of

Table 1 Survey practices and sample physicians

A: Number of survey practices and physicians by cohort

MRI acquisition year	Number of practices	Practices with >50 % physician ID match	Number of physicians
Comparison			
Without MRI thru 2010	442	263	1790
2011-2013	23	19	720
Total	465	284	2510
Treatment			
2007	30	21	226
2008	15	12	206
2009	18	16	283
Total	63	49	715

Sources: AAOS Survey Data, 2012; CMS NPPES Downloadable File [39], see text

providers with valid UPIN or NPI) were statistically significant in the model ($p < 0.01$)

The logistic regression index value (i.e., $X\beta$) for each practice was used as a practice-level propensity score for onsite MRI acquisition. For PS matching of MRI to non-MRI practices, there is a classic trade-off between the degree to which PS matching achieves “balance” across covariates for case and comparison practices and the number of case practices retained in the PS-matched sample to be used in the analysis [44]. In this case, because MRI practices are fundamentally different from non-MRI practices in terms of a key practice characteristic (specifically, practice size), restricting the matching of non-MRI practices to comparable MRI practices based on an exact or near exact PS would have resulted in a very small sample of matched case-comparison practices. Adding more covariates to the PS model would not enhance the prospects for more precise PS matches given the predominance of practice size in predicting MRI acquisition.

To address the trade-off between covariate balance and sample size, we used PS caliper matching to avoid selecting a non-MRI practice as a match for an MRI practice when the practices were too dissimilar to constitute a reasonable match, while retaining a reasonable sample size. Specifically, we used one-to-one PS caliper matching (without replacement), with the caliper restricting the acceptable difference in PS to be less than 25 % of the standard deviation of the PS distribution across all practices [45]. By imposing this PS caliper restriction, 23 MRI practices and 23 matched non-MRI comparison practices were identified, with a total of 252 and 181 affiliated providers, respectively (Table 2).

Medicare claims data

Three years of Medicare Part B utilization data were obtained for each of the 433 physicians from the three MRI “treatment” cohorts (2007, 2008, and 2009) and the three matched non-MRI comparison cohorts. For example, for each of the 100 physicians in the 2007 MRI treatment group and each of 67 physicians in the 2007 non-MRI comparison group, we accumulated all Medicare claims

containing each individual UPIN/NPI for one year before and one year after the MRI acquisition cohort year. Specifically, we obtained all patient claims from Medicare carrier files for 2006 and 2008 associated with 167 physician UPIN/NPIs. With duplicate UPIN/NPIs associated with physicians with multiple practice locations, there were a total of 287 physician IDs (UPIN/NPIs) in the “finder file” (used to link providers to their claims) for calendar years 2006 and 2008 (i.e., one year before and one year after 2007), with 631,510 claims and 452,108 Medicare patient visits in the Medicare carrier file with one of the 287 UPIN/NPIs. Among these 287 UPIN/NPIs, 182 UPIN/NPIs had a business zip code in Medicare carrier file that matched the practice zip code in the AAOS survey (see Fig. 1). The sample of physicians with UPIN/NPI zip codes that match the AAOS survey zip code are used as the principal sample for the analysis of patterns of MRI use in the Medicare claims data.

An analogous approach was used to aggregate Medicare claims data for the physicians in the 2008 and 2009 cohorts. Specifically, the pre-MRI year Medicare claims data are for the calendar year 2007 and 2009 for the 2008 and 2009 cohorts, respectively, and the post-MRI year Medicare claims data are for the calendar year 2009 and 2010 respectively.

Despite our efforts to use all available CMS data to confirm the practice affiliation of providers obtained from the AAOS practice survey data, the possibility of errors in the assignment of specific providers to specific practices at the time of first onsite MRI acquisition remains. To assess the extent of any assignment errors, all 46 practices included in the final sample of matched onsite MRI and non-MRI practices were re-surveyed. The MRI practices were asked to confirm that the practice acquired its first onsite MRI in the indicated MRI year (e.g., 2008 for MRI practices in the 2008 cohort), and non-MRI practices were asked to confirm that the practice did not have onsite MRI capacity in any of the study years for that practice (e.g., 2007–2009 for a non-MRI practice in the 2008 cohort). The re-survey instrument also provided a list of UPIN/NPI numbers specific to each of the 46 practices (obtained from the initial survey). Practices were asked to confirm whether the listed providers were affiliated with the practice during all of the specific study years for that practice (e.g., 2007–2009 for a practice with MRI year 2008, or a non-MRI practice matched to a 2008 MRI practice).

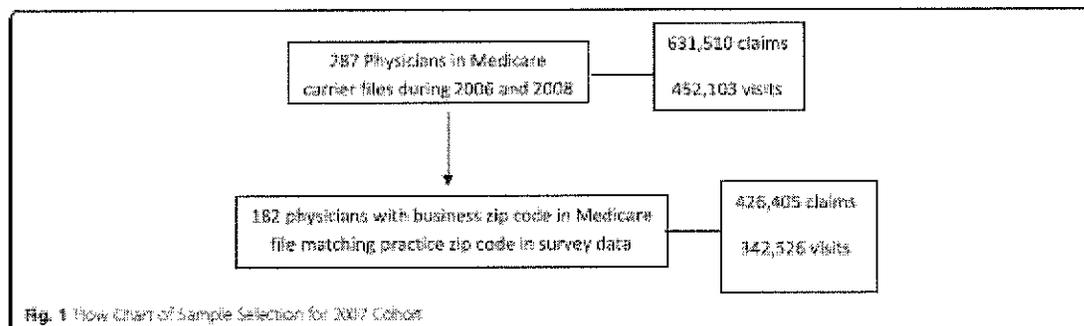
A total of 20 of the 46 practices responded to the re-survey (46 % response rate). All of the responding practices confirmed that the MRI or non-MRI status in the survey was correct. The respondents also confirmed that about 90 % of the provider ID numbers from the original survey were affiliated with the practice in both the pre- and post-MRI year for the practice. While the results of

Table 2 Survey practices and sample physicians

ii Number of physician and practice among treatment and control group

	Number of practices			Number of physicians		
	Comparison	Treatment	Total	Comparison	Treatment	Total
2007	11	11	22	67	100	167
2008	4	4	8	17	35	52
2009	8	8	16	97	117	214
Total	23	23	46	181	252	433

Source: AAOS Survey Data, 2012; CMS NPPES Downloadable File (39) see text



the re-survey suggest that provider timing assignment errors in the principal provider sample were not common, all regression models using the principal provider sample were re-estimated using a restricted sample of providers with a confirmed practice affiliation for the pre- and post-MRI years.

Analytic approach

The unit of analysis for the Medicare claims data analysis is the individual physicians affiliated with the MRI treatment practices and the matched non-MRI comparison practices. The analysis focuses on the difference in the volume of MRI exams ordered by each physician during the calendar year after the year of onsite MRI acquisition and the volume of MRI exams ordered by the same physician during the calendar year before MRI acquisition. The intent is to assess the “steady state” volume of MRI exams with and without onsite MRI, as the volume of MRI exams immediately after the acquisition of onsite MRI capacity may be atypical if practices work off “pent up” demand for MRI exams when the onsite MRI capacity first becomes available.

The analytic approach makes use of a multivariate regression model of the general form

$$\begin{aligned} \Delta MRI_{i,j,r} &= (MRI_{i,j,r,t} - MRI_{i,j,r,t-1}) \\ &= \alpha + \beta \text{Onsite}_{j,r,t} + \phi \text{Practice}_{j,r,t} \\ &\quad + \psi \text{Area}_{r,t} + \epsilon_{i,j,r} \end{aligned} \tag{1}$$

In Eq. (1), the term “ $\Delta MRI_{i,j,r}$ ” indicates the difference in the volume of MRI exams in the Medicare claims data for an individual physician (i) in a specific practice (j) located in a specific county (r) for one year post-onsite-MRI acquisition ($t + 1$) and one year pre-onsite-MRI acquisition ($t - 1$). For physicians in the matched non-MRI comparison practices, the MRI acquisition year for the matched MRI practice (t) is used as a pseudo-MRI year to define the pre- and post-MRI-year volume of MRI exams. The term “ $\text{Onsite}_{j,r,t}$ ” is a binary variable equal to one for physicians in practices acquiring onsite MRI

capacity in year t and zero for physicians in the matched non-MRI practices.

The modeling approach is a variant of the familiar “differences in differences” approach [46]. By focusing on the change in the volume of MRI exams for individual physicians, each physician acts as his or her own “control,” in that any specific characteristics of the individual physician (e.g., practice style, patient case mix) that might influence the physician’s use of MRI exams but remain essentially constant over the 3 year pre/post period will “difference out” when examining the change in the volume (post-pre) onsite MRI acquisition. Thus, the dependent variable is only affected by factors that vary over time. Beyond the change in onsite MRI status, general market conditions for orthopedic services could have changed over the pre- and post-MRI periods. Thus, a multivariate model is estimated that also adjusts for differences between MRI and non-MRI practices in practice characteristics (“ $\text{Practice}_{j,r,t}$ ”) and county-level practice area characteristics (“ $\text{Area}_{r,t}$ ”) that remains after PS matching. Finally, α , β , ϕ , and ψ in Eq. (1) represent parameters to be estimated by the regression model, and $\epsilon_{i,j,r}$ represents an error term. The estimation procedure used accounts for the likely correlation in errors among physicians in the same practices.

As noted, a PS matching procedure was used to provide a rationale for the selection of the MRI and comparison non-MRI practices to be used to collect Medicare claims data for the providers in the selected MRI and non-MRI practices. If PS matching had achieved an exact or near exact match between case and comparison practices, differences in observed practice characteristics between the physicians in the treatment and comparison groups might have been negligible, making covariate adjustment for practice characteristics in a multivariate regression unnecessary. However, PS matching of MRI practices to non-MRI practices is approximate in this application. Coupled with the fact that the level of analysis is the individual providers in the matched practices, some significant differences between the practice characteristics of the physicians in the MRI practices and physicians in matched non-MRI

practices remain, as shown in Table 3. Physicians in MRI-acquiring practices had higher Medicare MRI volume than physicians in non-MRI practices both one year before and one year after the MRI acquisition year. The MRI-acquiring practices were larger (in terms of number of providers) and were located in areas experiencing growth in per capita income, compared to non-MRI practices. Given these differences, some covariate adjustment in a multivariate regression model may be needed [47]. Thus, we estimate alternative specifications of Eq. (1) with and without different categories of covariates included in the model.

Table 3 Sample means for physician practice samples, by on-site MRI status

	All (n = 493)	MRI (n = 252)	No MRI (n = 181)
<i>MRI Volume^a (% Medicare Visits)</i>			
Pre-MRI year	1.151	1.460	0.585
Post-MRI year	1.312	1.530	0.919
ΔPost-Pre	0.161	0.071	0.324
<i>Ortho-MRI Volume^b (% Medicare Visits)</i>			
Pre-MRI year	1.066	1.391	0.480
Post-MRI year	1.239	1.428	0.809
ΔPost-Pre	0.173	0.037	0.327
<i>MRI Year (%)</i>			
2006	38.55	44.72	27.43
2007	36.54	31.21	18.14
2008	34.91	24.08	54.42
<i>Number of providers (%)</i>			
1-2	2.57	1.47	3.90
3-5	6.64	5.90	7.96
6-10	26.86	12.53	52.65
>10	64.14	80.10	35.49
<i>Practice Payer Mix (%)</i>			
Medicare	27.07	35.13	38.77
Private Insurance	46.90	47.83	45.72
Workers' Comp	12.50	12.10	13.64
Other	13.24	13.94	13.38
<i>Area Characteristics (Post-Pre)</i>			
ΔPer capita income (\$1000s)	1.211	1.916	-0.058
ΔTop age 65+ (%)	0.619	0.467	0.817
ΔUnemployment (%)	2.850	2.461	3.578
ΔMMDs/1000/Population	-0.0018	-0.0045	0.0032

Sources: Medicare Claims Data, AACS Survey Data, 2012; Area Resource File (see text)

^aHCPCS codes: 71252, 73278, 73718, 74183, 77089, 70543, 70551, 70553, 72141, 72146, 72148, 72156, 72157, 72158, 72165, 72167, 73220, 73221, 73223, 73225, 73720, 73721, 73722, 73723, 70336, 70340, 70342, 70342, 71350, 71351, 72142, 72147, 72149, 72196, 73219, 73719, 74181, 74182, or 77084

^bHCPCS codes: 72141, 72146, 72148, 72156, 72157, 72158, 72167, 73220, 73221, 73223, 73720, 73721, 73722, 73723, 73725, 73726, 73727, 73728, or 73729

The primary measure of "AMRI_{it}" is the difference in the total number of Medicare MRI exams (post-pre) ordered by each physician as a percentage of all Medicare outpatient visits for each physician. (See Table 3 for specific HCPCS codes defining MRI exams.). An alternative measure focuses on the post/pre difference in MRI exams with diagnosis codes indicative of orthopedic conditions ("Ortho-MRI") as a percentage of all Medicare outpatient visits for each physician (see Table 3). We also analyze the post-pre difference in the absolute (total) number of Medicare MRI exams and Medicare orthopedic-MRI exams for each physician.

All multivariate regression models were estimated using Stata Version 13 (<http://www.stata.com/stata13/>), employing the "cluster" option (to account for physicians in the sample affiliated with the same practice) and the "robust" standard error option (to account for other potential departures from homoscedasticity by using the Huber-White robust standard error estimator).

Results

Table 4 provides model estimates of the effect of onsite MRI acquisition ("Onsite MRI") on the change in total Medicare MRI exams as a percentage of total Medicare outpatient visits for specific physicians over the post/pre MRI year period. Column 1 of Table 4 reports the estimated impact onsite MRI capacity acquisition on the change in Medicare MRI volume as a percentage of Medicare visits in a regression model with no covariate adjustment (other than MRI cohort year). The model specification in column 2 adds measures of practice size as covariate adjusters, column 3 also includes practice payer mix variables, and column 4 adds the post-pre change in levels of county-level practice area characteristics.

The point estimate for the coefficient of the onsite MRI variable in each of these alternative regression model specifications is negative, which suggests the change in Medicare MRI volume for providers in MRI practices was lower than the change for non-MRI practices over the same time period, but all of the estimated coefficients are small in magnitude and not statistically significant ($p > 0.05$).

Focusing briefly on estimated coefficient values for other covariates included in the model reported in column 4, the estimated coefficients of the MRI cohort year variables suggest that the change in MRI volume for providers in the 2008 cohort was 2.2 percentage points greater than the change for providers in the reference-category 2007 cohort ($p = 0.038$), adjusting for other variables included in the model. A 1 percentage point greater Medicare share in the practice payer mix was associated with a 0.09 percentage point greater change in provider Medicare MRI volume ($p = 0.010$), and a 1 percentage point greater private insurance share in the

Table 4 Estimated difference in percent medicare visits for MRI exams for physicians Post/Pre Onsite MRI acquisition relative to physicians without onsite MRI, 2007–2009 cohorts

AMRIs as % Visits	Model 1		Model 2		Model 3		Model 4	
	Coefficient	p-value	Coefficient	p-value	Coefficient	p-value	Coefficient	p-value
Onsite MRI	-0.330	0.486	-0.139	0.753	-0.237	0.307	-0.468	0.161
MRI Year								
2007	Reference	-	Reference	-	Reference	-	Reference	-
2008	1.565	0.063	1.570	0.060	0.817	0.125	2.175	0.038
2009	0.424	0.454	0.567	0.323	0.227	0.533	1.157	0.067
Number of providers								
1-2	-	-	Reference	-	Reference	-	Reference	-
3-5	-	-	-1.930	0.080	-1.121	0.398	-1.086	0.448
6-10	-	-	-2.199	0.037	-2.143	0.076	-1.852	0.095
>10	-	-	-2.395	0.073	-2.015	0.072	-1.907	0.083
Practice Payer Mix (%)								
Medicare	-	-	-	-	0.0734	0.006	0.0926	0.010
Private insurance	-	-	-	-	0.0660	0.004	0.0634	0.006
Worker Comp	-	-	-	-	0.0289	0.511	0.0442	0.353
Other	-	-	-	-	Reference	-	Reference	-
Aged Characteristics								
Age per cap inc (\$1000)	-	-	-	-	-	-	0.072	0.278
Age age 65+ (%)	-	-	-	-	-	-	0.516	0.198
All-employment (%)	-	-	-	-	-	-	-0.246	0.216
AMCs/1000 Pop	-	-	-	-	-	-	-1.215	0.418
F-Statistic (p-value)	1.37	0.266	1.81	0.125	2.80	0.013	2.93	0.007

Sources: see text

practice payer mix was associated with a 0.06 percentage point greater change in provider Medicare MRI volume ($p = 0.006$). None of the remaining estimated coefficients were statistically significant at the $p < 0.05$ level.

To assess whether the finding of a lack of association between onsite MRI acquisition and changes in the volume of Medicare MRI exams is robust to model specification changes, models were estimated using four alternative measures of the change in provider MRI exam volume: 1) the change in MRI exams as a percentage of all Medicare patient visits; 2) the change in orthopedic-related MRI exams as a percentage of all Medicare

patient visits; 3) the absolute change in the number of MRI exams; and 4) the absolute change in the number of orthopedic-related MRI exams.

We also estimated models using the principal study sample and an alternative subsample of providers confirmed by the AAOS practice re-survey to have been practicing in the study practices during both study years. Point estimates of the coefficient of the onsite MRI variable and their associated p -values (for a two-tailed test of the null hypothesis that the true coefficient equals zero) across these alternative model specifications are summarized in Table 5. [Full model results are available on request].

Table 5 Summary of estimated coefficient for "Onsite MRI" for alternative measures of the difference in medicare MRI volume and alternative provider samples

MRI volume change measure	Principal provider sample (N = 433)		Confirmed provider sample (N = 371)	
	"Onsite MRI"	p-value	"Onsite MRI"	p-value
ΔMIRs as % Visits	-0.468	0.161	-0.604	0.273
ΔOrtho MIRs as % Visits	-0.399	0.210	-0.287	0.128
ΔNumber of MIRs	2.165	0.420	1.591	0.310
ΔNumber of Ortho-MIRs	0.102	0.977	0.152	0.507

Sources: see text

None of the point estimates of the onsite MRI coefficient are statistically significant ($p > 0.1$) across all of alternative model specifications reported in Table 5. Results using the principal provider sample are similar (in terms of coefficient point estimates) to results using a sample restricted to providers with their practice location during the study years confirmed by the practice re-survey. Thus, any potential errors in the assignment of specific physicians to specific practices appear to be too infrequent to have a substantive impact on model results.

Discussion

Economic theory predicts, and our results confirm, practices using imaging more intensively were more likely to acquire onsite MRI capacity (i.e., acquiring practices had higher MRI volume than non-MRI practices before MRI acquisition). This creates a sample selection (or endogeneity) issue when attempting to assess the causal impact of onsite MRI acquisition on MRI volume. By using a differences-in-differences model focusing on the change in MRI volume for individual physicians, any individual physician or practice characteristics (observed or unobserved) potentially affecting MRI volume that are invariant over the pre- and post- time periods “difference out” when analyzing the change in MRI volume. Covariate adjustment using proxy measures of physician “practice style” is not needed. Our model also adjusts for changes in observable practice area characteristics over time. To the extent unobservable time-varying factors exist, such factors are likely to affect the demand for imaging services and the likelihood of onsite MRI acquisition in the same direction. Thus, any remaining bias in our analysis relating to the sample selection issue would be toward finding a positive association between MRI acquisition and MRI volume.

None of our model results suggest any substantive change in Medicare MRI volume one-year post- onsite-MRI-acquisition and one-year pre- onsite-MRI-acquisition for physicians in MRI-acquiring practices relative to physicians in the non-MRI comparison practices. This finding is inconsistent with results reported in much of the literature focused on the issue of “self-referral” for imaging services.

The differences in findings may relate to differences in research designs, particularly as they relate to sample selection issue, and the specific measures of MRI acquisition used across studies. Some existing studies rely on proxy measures of the existence or size of ownership interests in specific ancillary services for individual physicians due to a lack data for specific provider interests. For example, close to a dozen published studies (e.g., Hughes et al. [12], Mitchell [13]) use an individual physician’s referral patterns to “impute” physician ownership status for individual physicians. Specifically, physicians

with a relatively high share of their overall referrals going to a physician-owned facility are simply assumed to have ownership interest in the facility. These studies provide little or no evaluation of the validity of this imputation process for identifying individual physician ownership status, but even if approximately valid, the use of an imputed ownership status indicator based on patterns of referrals to predict patterns of referrals presents what should be a rather obvious and substantial threat to the validity of any resulting inferences about the causal effect of ownership status on referral volume. In contrast, our analysis uses direct and verified measures of access to onsite MRI capacity for individual providers.

A simple cross-sectional design is used in close to a dozen published studies, including Hillman et al. [10] and Paxton et al. [16]. These studies compare imaging volume for physicians with and without ownership interest in imaging capacity, not before and after the acquisition of ownership interest. Our results indicate that the physicians in practices acquiring onsite MRI capacity had higher MRI volume before MRI acquisition than physicians in similar practices that did not subsequently acquire onsite MRI capacity. Thus, simple cross-sectional comparisons are likely to yield a spurious positive association between onsite MRI acquisition and MRI volume owing to the endogeneity of onsite MRI capacity acquisition.

Still other past studies, such as Sharpe et al. [17], focus on imaging volume within practices acquiring imaging capacity over time, without an appropriate contemporaneous comparison group. Our results indicate that MRI volume increased over time for both MRI and non-MRI practices. Without an appropriate comparison group, our results might have suggested (incorrectly) that MRI acquisition per se was associated with an increase in MRI volume.

Finally, much of the early literature examining physician self-referral for imaging services focused on the general issue of physician investment interests in imaging facilities, including free-standing (off-site) imaging centers. As noted, organizational economics theory suggests that there are likely to be advantages (in terms of lower monitoring and transactions costs) associated with the ownership of imaging capacity for providers making more extensive use of imaging in their practices, compared to less imaging-intensive providers. However, these advantages are likely to more substantive for onsite capacity compared to off-site capacity. In other words, the degree of organizational control may be somewhat greater for owned off-site capacity compared to non-owned offsite capacity, but the degree of organizational control is likely to be far greater for owned onsite capacity compared to owned off-site capacity. Thus, the process of physician self-selection into

ownership of onsite imaging capacity reflected in our data may be different than the process of self-selection into imaging capacity ownership overall present in older studies.

Limitations

Although we used a web-based survey of orthopedic surgery practices to identify specific providers affiliated with practices at the time the practice first acquired onsite MRI capacity, and then used the CMS National Plan and Provider Enumeration System (NPPES) Full Replacement Monthly NPI File data and a re-survey of the final sample of practices included in the analysis to confirm that physicians identified as affiliated with an MRI practice in the survey data actually were affiliated with the practice one year before and one year the practice's MRI-year, the potential for errors in assignment of specific physicians to specific practices remains. If these assignment errors are common, the results of the claims data analysis of the change in MRI volume would be biased toward a finding of "no effect" of onsite MRI capacity.

While the practice re-survey confirmed 90 % of provider practice affiliations, the re-survey response rate was 43 %, so a similar rate of confirmation might not have been obtained from practices not responding to the re-survey. However, the fact that model results restricted to a sample of providers with confirmed practice affiliations produced results similar to results using the full (principal) provider sample provides some assurance that the potential for provider assignment errors is not a substantial limitation of the study.

The sample of providers included in the study was derived from a PS matching approach applied at the practice level using a specific caliper intended to provide a reasonable trade-off between covariate balance and the number of MRI practices retained in the final sample. Selection of a smaller caliper would have produced fewer matches, and thus fewer providers in our analysis sample, whereas a larger caliper would have produced more matches, and thus a larger provider sample. It is possible that a different practice-level PS matching approach yielding a different sample of providers in MRI and non-MRI practices would have produced different results. However, the fact that model results using the full (principal) provider sample were similar to model results using a sample of providers with re-survey confirmed practice affiliations suggests that the results are not highly sensitive to sampling approach used to select the specific providers included in the analysis.

Obviously, our analysis of Medicare claims data only provides information about patterns of MRI use within the Medicare segment of each physician's patient population. No inference about whether onsite MRI acquisition affects patterns of MRI use for other payers is possible. Past studies have shown that geographic variation in the

use of specific services for Medicare patients is not always reflective of patterns of use in non-Medicare populations [48]. Orthopedic surgery practices on average derive about one-third of their total practice revenues from Medicare. While this is not an inconsequential share, this study cannot assess the impact of onsite MRI capacity on use patterns for about two-thirds of the typical orthopedic surgery practice population. Even so, an assessment of the impact of onsite MRI capacity on use patterns for Medicare patients has direct relevance for public policy, as the Stark laws only apply to Medicare and Medicaid patients.

Moreover, commercial payers, especially managed care plans, typically employ stricter MRI utilization controls and incentives than the Medicare program [49]. Thus, rather than a limitation, our choice of examining the Medicare population could alternatively be viewed as a conservative decision; if provider ownership in onsite imaging capacity has a causal impact on imaging volume, we would expect the magnitude of the effect to be larger in the comparatively "less managed" Medicare population relative to more active care management in managed care markets. Our null finding for the Medicare population suggests the likelihood of a null finding in managed care population.

Conclusion

Our analysis of Medicare claims data employed outpatient claims data for the 2007, 2008, and 2009 cohorts of physicians in practices which acquired onsite MRI capacity and physicians in matched non-MRI practice. The claims analysis focused on the change in Medicare MRI volume one-year post-onsite-MRI-acquisition and one-year pre-onsite-MRI-acquisition for physicians in MRI practices relative to physicians in the non-MRI comparison practices. In all of the Medicare MRI volume change models estimated, the estimated impact of onsite MRI acquisition on the change in Medicare MRI volume is consistently small and not statistically significant. Thus, our data analysis provides no empirical support for the proposition that acquisition of onsite MRI capacity within an orthopedic surgery practice induces an increase in the rate of MRI use for Medicare patients among practice providers, relative to physicians in practices without MRI capacity over the same time period.

Competing interests

This research was conducted by Oxford Outcomes, Inc. (now ICON plc) through a contract with the American Academy of Orthopaedic Surgeons (AAOS). No additional competing interests to report.

Authors' contributions

All three authors confirm that we have made individual contributions to the completion of this manuscript to qualify as authors under ICMJE guidelines. Specifically, all of us: 1) have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) have been involved in drafting the manuscript or revising it critically for important intellectual content; 3) have given final approval of the version to

be published; and d) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved."

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EXHIBIT V



Connecticut Orthopaedic Specialists

AND OUR DIVISIONS

The Orthopaedic Group

OrthopedicHealth



Center For Orthopaedics



ORTHOPEDICS & SPORTS MEDICINE

2016 MRI Non Operating Hours

Hamden MRI	ACR Tests	Weather Cancellation	Machine Maintenance	Air Conditioner Repair
Jan 23rd		14		
Feb 5th			6	
Feb 6th			2	
Feb 7th			2	
Mar 8th			3.5	
Mar 31st			1	
Apr 1st			1	
Apr 18th	1.5			
Apr 19th	3			
May 31st			1	
Jun 1st			1	
Aug 11th			1	
TOTAL HAMDEN	4.5	14	18.5	

2016 MRI Non Operating Hours

Branford MRI	<i>ACR Tests</i>	<i>Weather Cancellation</i>	<i>Machine Maintenance</i>	<i>Air Conditioner Repair</i>
Jan 13th			5.5	
Jan 23rd		14		
Feb 17th				1.5
Feb 26th			2.5	
Mar 4th			4	
Apr 11th			3	
Apr 12th			4	
Apr 18th	1.5			
Apr 19th	3			
Apr 20th			3	
Jun 7th			1.5	2.25
Aug 9th				2.5
Sep 22nd			4	
Sep 23 rd				2.25
Nov 8th				2.25
Nov 30th			5	
Dec 13th			3	
Dec 20th			5	
Dec 21st			3.5	
TOTAL BRANFORD	4.5	14	44	10.75

Combined Branford and Hamden MRI Non Operating Hours

Total number of non operating
hours:

110.25