

STATE OF FLORIDA
BOARD OF MEDICINE

Final Order No. DOH-08-0036-DSMOA
FILED DATE - 10-9-08
Department of Health
By: Racquel B...
Deputy Agency Clerk

IN RE: PETITION FOR DECLARATORY STATEMENT

JACKSONVILLE HEART CENTER, P.A.

AMENDED FINAL ORDER

This matter came before the Board of Medicine (hereinafter the "Board") on October 6, 2007, in Orlando, Florida, for consideration of the above-referenced Petition for Declaratory Statement. The Notice of Petition for Declaratory Statement was published on September 21, 2007, in Vol. 33 , No. 38, of the Florida Administrative Weekly.

In its petition JACKSONVILLE HEART CENTER, P.A. (Jax Heart) inquires as to whether it may operate a sleep study center solely for the use of its patients without running afoul with any provision of Section 456.053, Florida Statutes, (Patient Self-Referral Act of 1992).

FINDINGS OF FACTS

1. Jax Heart is a group practice comprised of seventeen (17) cardiovascular physicians licensed in Florida who provide comprehensive high quality cardiovascular care to its patients. Jax Heart proposes to establish an eight (8) bed sleep center (Sleep Center) as part of its medical practice wherein it will provide sleep studies and treatment for sleep disorders solely to its patients.

2. A sleep study is a series of non-invasive low risk tests that monitor and record what happens to a person's body during sleep. A sleep study can record a variety of information, including the brain's electrical activity, muscle activity, heart rate and breathing. This information can be used to diagnose or rule out a potential sleep disorder which often is related to impaired cardiac function. Untreated sleep disorders can contribute to the development of or exacerbate cardiovascular diseases such as hypertension, congestive heart failure, cardiac arrhythmias and stroke.

3. There are no safety issues with sleep studies. Having a sleep study is safer for the patient than sleeping at home since the patient's heart rhythm and breathing are monitored by an appropriately trained technologist who is present and can manage any problems that may occur.

4. Jax Heart intends to employ a full-time physician who is board-certified in sleep medicine. As a member of Jax Heart, the board certified physician will provide a full range of services which include, but are not limited to, medical care, consultations, diagnosis, treatment, interpretation of sleep studies, and oversight of the Sleep Center as its Medical Director. Any patients identified as a candidate for a sleep study would be evaluated by the Jax Heart board certified sleep physician to determine medical necessity.

5. A Jax Heart physician will be present on-site and immediately available when sleep studies are performed during normal business hours, 9:00 a.m. until 5:00 p.m. For sleep studies performed after normal business hours, a Jax Heart physician would be on-call and immediately available by phone. In the event that the Jax Heart physician's physical presence was required, the Jax Heart physician could be at the Sleep Center within thirty (30) minutes.

6. Sleep studies would be performed by a registered polysomnographic technologist (sleep technologist) employed by Jax Heart and under the supervision of the Medical Director and other Jax Heart physicians. The sleep technologist would be credentialed by the Board of Registered Polysomnographic Technologists.

7. It is important for a sleep study to mimic a patient's normal sleeping pattern, and therefore, most of the sleep studies will be conducted at night when most patients typically sleep. Jax Heart will employ sleep technologists for day and night shift schedules but a physician will not be present on the premises or in the office in the evenings.

CONCLUSIONS OF LAW

8. The Board of Medicine has authority to issue this Final Order pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

9. The Petition filed in this cause is in substantial compliance with the provisions of 120.565, Florida Statutes, and Rule 28-105.002, Florida Administrative Code.

10. The Petitioner's inquiry revolves around the issue of whether a patient referral by Jax Heart, a group practice as defined by Section 456.053(3)(h), Florida Statutes, to its sleep center constitutes a referral prohibited by Section 456.053(5), Florida Statutes.

11. Generally, the Patient Self-Referral Act prohibits health care providers from referring patients for additional health services to entities in which the health care provider has a financial interest. Section 456.053(5) reads in part as follows:

(a) A health care provider may not refer a patient for the provision of designated health services to an entity in which the health care provider is an investor or has an investment interest. (b) A health care provider may not refer a patient for the provision of any other health care item or service to an entity in which the health care provider is an investor

However, under the Patient Self-Referral Act some orders, recommendations or plans of care do not constitute a prohibited referral by a health care provider.

12. Section 456.053(3)(o) defines a "referral" as follows:

(o) "Referral" means any referral of a patient by a health care provider for health care services, including, without limitation: 1. The forwarding of a patient by a health care provider to another health care provider or to an entity which provides or supplies designated health services or any other health care item or service; or 2. The request or establishment of a plan of care by a health care provider, which includes the provision of designated health services or other health care item or service.

The very same subsection, however, sets forth a number of circumstances involving physician orders, recommendations or plans of care that do not constitute a "referral" by a health care provider. The exception relevant to this matter found in Section 456.053(3)(o) 3.f., reads in part as follows:

3. The following orders, recommendations or plans of care shall not constitute a referral by a health care provider:

...

f. By a health care provider who is the sole provider or member of a group practice for designated health services or other health care items or services that are prescribed or provided solely for such referring health care provider's or group practice's own patients, and that are provided or performed by or under the direct supervision of such referring health care provider or group practice
(emphasis added)

13. Jax Heart is clearly a group practice health care provider of health care services and the Sleep Center only accepts patients from Jax Heart. The key issue to be addressed in responding this petition is whether the services provided by the Sleep Center are being provided under the "direct supervision" of Jax Heart. If the Sleep Center does provide services under the direct supervision of Jax Heart, the Petitioner's proposed arrangement does not constitute a "referral" that is precluded by Section 456.053(5), Florida Statutes.

14. The Board recognizes that under current Medicare guidelines, physicians are only required to provide "general" supervision of sleep studies, which means the physician is not required to be physically present during the testing. See, Medicare Carriers Manual Part 3, Section 2070. However, in order to benefit from the exception set forth in Section 456.053(3)(o) 3.f., Florida Statutes, the services must be provided under the "direct supervision" of the referring health care provider.

15. Under Florida law, the term "direct supervision" is defined in Section 456.053(3)(e) as:

(e) "Direct supervision" means supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.

The phrase "present in the office suite" is further defined in Section 456.053(3)(p) as:

[T]he physician is actually physically present; provided, however, that the health care provider is considered physically present during brief unexpected absences as well as during routine absences of a short duration if the absences occur

during time periods in which the health care provider is otherwise scheduled and ordinarily expected to be present and the absences do not conflict with any other requirement in the Medicare program for a particular level of health care provider supervision.

16. Under the scenario set forth in Jax Heart's petition, the facility's Medical Director, a board certified sleep physician, will only be on the premises from 9:00 a.m. through 5:00 p.m., but the Sleep Center will be conducting most of its sleep studies in the evening when most patients typically sleep. The sleep studies conducted in the evening will be conducted and monitored by sleep technologists but a physician will not be physically present on the premises at such times.

17. The regularly scheduled absence of a physician on the premises during the evening hours when most of the sleep studies will be conducted cannot be reasonably construed to constitute a "brief unexpected absence" or a "routine absence[s] of a short duration" that "occur[s] during time periods in which the health care provider [physician] is otherwise scheduled and ordinarily expected to be present."

18. Given the facts and analyses set forth above, the Board is of the opinion that because the services to be provided at the Petitioner's Sleep Center will not be provided under the direct supervision of Jax Heart, Petitioner's proposed referral of patients to its Sleep Center is precluded by Section 456.053(5), Florida Statutes.

19. The Board's response to this Petition responds solely to the question propounded by the Petitioner and only addresses issues regarding the practice of medicine. The Board's conclusion is based solely on the Board's application of the factual circumstances outlined in the Petition to the pertinent statutory and rule provisions set forth above.

WHEREFORE, based on the foregoing, the Board hereby finds that Jacksonville Heart Center's proposed referral arrangement outlined in its petition is precluded by Section 456.053(5), Florida Statutes.

This Final Order shall become effective upon filing with the Clerk of the Department of Health.

DONE AND ORDERED this 9th day of January, 2008.

BOARD OF MEDICINE



Larry McPherson, Jr., Executive Director
for H. Frank Farmer, Jr., M.D., Chair

NOTICE OF APPEAL RIGHTS

Pursuant to Section 120.569, Florida Statutes, Respondents are hereby notified that they may appeal this Final Order by filing one copy of a notice of appeal with the Clerk of the Department of Health and the filing fee and one copy of a notice of appeal with the District Court of Appeal within 30 days of the date this Final Order is filed.

CERTIFICATE

OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U. S. Mail to: Elizabeth D. Shaw, Esquire and Rick M. Reznicek, Esquire, Reznicek, Fraser & Hastings, P.A., 240 Ponte Vedra Park Drive, Suite 150, Ponte Vedra Beach, FL 32082; and by

interoffice mail to Edward A. Tellechea, Senior Assistant Attorney General, PL-01 The Capitol, Tallahassee, Florida 3239-1050; and Josephina Tamayo, General Counsel, Department of Health, 4052 Bald Cypress Way, BIN A02, Tallahassee, Florida 32399-1703, on this 9 day of January, 2008.

Kellee Davidson

Deputy Agency Clerk

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
BOARD OF MEDICINE

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: *Racquel*
DATE 9-11-07

RECEIVED

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DEPT. OF LEGAL AFFAIRS
Administrative Law Bureau

In the Matter of:
A Petition for Declaratory Statement by
Jacksonville Heart Center, P.A., *et al*,
Before the State of Florida Board of Medicine

PETITION FOR DECLARATORY STATEMENT

The Petitioner, Jacksonville Heart Center, P.A., ("Jax Heart") including each of the individual licensed physicians named in the list attached hereto as Exhibit A, through undersigned counsel and pursuant to Section 120.565, Florida Statutes (2007), and Rule 28-105, Florida Administrative Code, hereby submits this Petition for Declaratory Statement to the State of Florida Board of Medicine (the "Board") for confirmation that the proposed arrangement would not constitute prohibited activity under Section 456.053, Florida Statutes, known as the Patient Self-Referral Act of 1992. In support thereof, Petitioner states the following:

I. Contact Information.

1. The name, address, telephone number and facsimile of the Petitioner is as follows:

Jacksonville Heart Center, P.A.
1905 Corporate Square Blvd.
Jacksonville, Florida 32216
Attn: Joel P. Schrank, M.D., F.A.C.C.
Telephone: (904) 425-4557
Facsimile: (904) 720-5225

2. The name, address, telephone and facsimile numbers of undersigned counsel as follows:

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Rick M. Reznicek, Esquire
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DEPT. OF LEGAL AFFAIRS
Administrative Law BureauII. Synopsis.

Jax Heart has extensively researched the need for testing for sleep disorders for its patients ("Sleep Study"). Diagnosis and treatment of sleep disorders can result in improved cardiac function for patients leading to a decrease in morbidity and mortality of patients. As part of its research, Jax Heart conducted an internal review of its current patients and identified that forty-four percent (44%) of its patients should have a Sleep Study to assist with the diagnosis and treatment of their cardiac problems. Locally, there is a wait time of often one month to have a Sleep Study performed in Jacksonville, Florida. In addition the rate for follow-up by local sleep centers at one year was an abysmal ten percent (10%). Jax Heart believes that the inclusion of Sleep Studies as an additional diagnostic tool in its practice is necessary to meet the developing standard of care for cardiology. The rationale for integration of sleep medicine into Jax Heart's practice is more fully explained in Exhibit B.

III. Factual Background.

1. Petitioner seeks an interpretation by the Board regarding Section 456.053, Florida Statutes, as applied to the following proposed arrangement:

a. Jax Heart is a group practice as defined in Section 456.053(3)(h), Florida Statutes. Jax Heart is comprised of seventeen (17) cardiovascular physicians licensed in Florida who provide comprehensive high quality cardiovascular care to its patients. To provide high quality care, Jax Heart must keep abreast of advances in technology for the detection and treatment of cardiovascular diseases. To do so, Jax Heart believes it is necessary to establish an eight (8) bed sleep center (the "Sleep Center") as part of its medical practice. Through the Sleep Center, Jax Heart would provide Sleep Studies and treatment for sleep disorders to its patients.

b. A Sleep Study is a series of non-invasive low risk tests that monitor and record what happens to a person's body during sleep. A Sleep Study can record a variety of information, including the brain's electrical activity, muscle activity, heart rate and breathing. This information can be used to diagnose or rule out a potential sleep disorder. Recent research studies have shown that more than half of patients with impaired cardiac function may also have a sleep disorder. Untreated sleep disorders can contribute to the development of or exacerbate cardiovascular diseases such as hypertension, congestive heart failure, cardiac arrhythmias and stroke. There are no safety issues with Sleep Studies. Having a Sleep Study is safer for the patient than sleeping at home since the patient's heart rhythm and breathing are monitored and the technologist is appropriately trained to manage any problems that may occur.

c. As part of establishing the Sleep Center, Jax Heart would employ on a full-time basis a physician who is board-certified in sleep medicine. As a member of Jax Heart, the board certified sleep physician would provide substantially the full range of services which he routinely provides, including, but not limited to,

medical care, consultations, diagnosis, treatment, interpretation of Sleep Studies, and oversight of the Sleep Center as its Medical Director. Any patients identified as a candidate for a Sleep Study would be evaluated by the Jax Heart board certified sleep physician to determine medical necessity.

d. Sleep Studies would be performed by a registered polysomnographic technologist ("Sleep Technologist") employed by Jax Heart and under the supervision of the Medical Director and other Jax Heart physicians. The Sleep Technologist would perform, monitor, and score the Sleep Studies. The Sleep Technologist would be credentialed by the Board of Registered Polysomnographic Technologists. It is important for a Sleep Study to mimic a patient's normal sleeping pattern. Accordingly, Sleep Studies would be performed during the day and night dependent on the patient's schedule, normal sleep cycle and type of test. As with other Sleep Centers, most of the Sleep Studies would be performed at night when the patient typically sleeps. Jax Heart would employ Sleep Technologists for day and night shift schedules.

e. Jax Heart would bill for both the technical and professional component of the Sleep Studies through the tax identification number of Jax Heart.

f. A Jax Heart physician would be present on-site and immediately available when Sleep Studies are performed during normal business hours. For purposes of this Petition, "normal business hours" means from 9:00 a.m. until 5:00 p.m. For Sleep Studies performed after normal business hours, a Jax Heart physician would be on-call and immediately available by phone. In the event that the Jax Heart physician's physical presence was required, the Jax Heart physician could be at the Sleep Center within thirty (30) minutes.

IV. Legal Authority.

1. The Patient Self-Referral Act of 1992 (hereinafter referred to as the "Self-Referral Act"), attached hereto as Exhibit C, governs the financial arrangements between referring health care providers and providers of health care services. Broadly speaking, the Self-Referral Act prohibits certain health care providers from referring patients for health care items or services to an entity in which the health care provider (or family member) has an investment interest, unless certain provisions are met.

2. The Self-Referral Act provides that certain orders, recommendations or plans of care do not constitute a referral by a health care provider. Although, there is not a specific exception for Sleep Studies, there is a group practice exception which would be applicable to the proposed arrangement. The group practice exception exempts from the definition of "referral" any orders, recommendations or plans of care:

(3)(o)(3)(f) ...By a health care provider who is the sole provider or member of a group practice for designated health services or other health care items or services that are prescribed or provided solely

for such referring health care provider's or group practice's own patients, and that are provided or performed by or under the direct supervision of such referring health care provider or group practice...(emphasis added)

3. To satisfy the group practice exception, the Self-Referral Act requires that all health care services be provided or performed by or under the *direct supervision* of such referring health care provider or group practice. "Direct supervision" means supervision by a physician who is *present in the office suite and immediately available* to provide assistance and direction throughout the time services are being performed. The Self-Referral Act defines "present in the office suite" as the physician is *actually physically present*; provided, however, that the health care provider is *considered physically present during brief unexpected absences as well as during routine absences of a short duration* if the absences occur during time periods in which the health care provider is otherwise scheduled and ordinarily expected to be present and the *absences do not conflict with any other requirement in the Medicare program for a particular level of health care provider supervision.*"

V. Analysis.

1. A report by the American Medical Association Council on Ethical and Judicial Affairs (the "Council) discussed the issue of physician ownership of medical facilities. The Council distinguished services provided within a physician's office and those provided in outside facilities. The Council stated,... "to the extent possible, physicians should not be in the business of profiting purely from their ability to refer patients to outside facilities. Such a practice is fundamentally different from deriving financial reward from treating patients in their offices or in outside health care facilities they have invested in at which they care for, or provide services to, their patients. When physicians provide care or services, they have direct responsibility for, and control over, the quality of the facility at which the care or services are provided." Council on Ethical and Judicial Affairs, American Medical Association, *Conflicts of Interest: Physician Ownership of Medical Facilities*, 267 JAMA 2366, 2368 (1992). See Exhibit D.

2. Under the proposed arrangement, Jax Heart would provide the Sleep Studies through its group practice in its office. Jax Heart would have direct control over the quality of the testing. Jax Heart would hire, train and be ultimately responsible, both financially and legally, for the staff, equipment and facility. Thus, Jax Heart would be directly responsible to ensure efficient and quality health care services for its patients.

3. Furthermore, there is no evidence that Sleep Studies are overutilized. The Council's report discussed a study by the Florida Health Care Cost and Containment Board that identified overutilization in clinical laboratory testing, diagnostic imaging and physical therapy. There was no report regarding overutilization of Sleep Studies.

4. In adopting the Self-Referral Act, the Florida Legislature identified four main concerns that create a potential conflict of interest when a physician has an investment interest in an entity to which the physician makes a referral. The Florida Legislature feared that the referral may (i) limit or eliminate competitive alternatives; (ii) result in overutilization of health care services; (iii) increase costs to the health care system; and (iv) adversely affect the quality of health care. Jax Heart understands the Florida Legislature's concerns and its duty to protect the people of Florida from unnecessary and costly health care. Jax Heart will specifically include certain safeguards to meet all the Florida Legislature's concerns, as described below:

a. Jax Heart would follow the Medicare criteria for medical necessity of ordering a Sleep Study. In addition, the board certified sleep physician would evaluate each candidate to determine whether the Sleep Study is medically necessary. Only patients approved by the Jax Heart board certified sleep physician will receive a Sleep Study. This additional check on the appropriateness of a Sleep Study should prevent overutilization. The Jax Heart board certified sleep physician will not have an ownership interest in Jax Heart and will not share in any profits from the Sleep Center. Therefore, the Jax Heart board certified sleep physician is not incentivized to approve Sleep Studies.

b. Jax Heart would provide each patient referred for a Sleep Study with a written disclosure form, informing the patient of: (i) the patient's right to obtain the Sleep Study from the sleep center of the patient's choice; (ii) the names and addresses of at least two alternative sleep centers where the patient may obtain the Sleep Study; and (iii) the patient's selection of another sleep center would not jeopardize the patient's ability to continue as a patient of Jax Heart.

c. Jax Heart would set its fees for Sleep Studies in accordance with Medicare and other third party payor fee schedules.

d. Jax Heart would comply with the AASM Standards and actively pursue accreditation by the AASM.

e. Jax Heart would monitor the quality, appropriateness and medical necessity of the Sleep Studies provided at the Sleep Center through its Quality Improvement Committee. The Quality Improvement Committee will be empowered to discipline those physicians who fail to meet its standards. Such discipline will include mandatory education, monetary fines and termination of employment.

Consequently, the provision of Sleep Studies by Jax Heart would actually lower health care costs and improve quality of care since the prompt diagnosis and treatment of sleep disorders can be the key to controlling a patient's other medical conditions. Research studies show that diagnosis and treatment of patients with obstructive sleep apnea ("OSA") results in a significant reduction in physician claims and hospitalizations. In fact, treatment of OSA in patients with cardiovascular and pulmonary disease markedly reduces the need for acute hospital

admission due to their cardiovascular and pulmonary conditions. Most important, the patients have improved quality of life. Copies of the referenced research studies are attached hereto as Composite Exhibit E.

5. We believe that the Florida Legislature required the higher level of "direct" supervision in the group practice exception to ensure that the health care services provided were indeed a part of the group practice. However, it is clear from the definition of "present in the office suite" that the Florida Legislature did not contemplate services which would be provided by a group practice *after* normal business hours. The fact that the health care provider is "*considered physically present during brief unexpected absences as well as during routine absences of a short duration*" demonstrates that the intent of the statute was to allow the health care provider to leave for lunch and to make rounds at the hospital during the day when the health care services were provided. This opinion is supported by the federal Stark Law which proposed a similar definition of direct supervision in the Stark II Proposed Rules and provided "lunch break" as an example of a routine absence. 66 Fed. Reg. 885 (Jan. 4, 2001). See Exhibit F. Other absences that would occur in a physician's office include; (i) hospital rounds; (ii) to attend on emergent surgery or invasive procedure; and (iii) Emergency Department call. Any of these absences could cause the physician to be away from the office for an extended period of time. Sleep Studies are a unique type of test since this primarily takes place at night when a person normally sleeps. Although there is nothing else in a physician's office which is analogous to a Sleep Study, a physician not being present at night while a Sleep Study is performed is not incompatible with the current standard of care.

6. When determining the level of physician supervision required for a procedure or diagnostic test, health care providers and insurance companies look to the Medicare guidelines as the recognized authority. Medicare sets forth three levels of physician supervision required for furnishing the technical component of diagnostic tests for a Medicare beneficiary who is not a hospital inpatient or outpatient:

a. General Supervision -- means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure.

b. Direct Supervision -- in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

c. Personal Supervision -- means a physician must be in attendance in the room during the performance of the procedure.

Sleep Studies are a safe non-invasive test. Thus, the Medicare guidelines only require physicians to provide "general" supervision of Sleep Studies, which means the physician is not required to be physically present during the testing. Medicare Carriers Manual Part 3, Section

2070 and First Coast Services Option Medicare B Update Third Quarter 2001. See Composite Exhibit G.

7. It is apparent that the Florida Legislature considered the importance of Medicare guidelines for physician supervision when it included language in the Self-Referral Act that the physician's absences "do not conflict with any other requirement in the Medicare program for a particular level of health care provider supervision." The Jax Heart physician's absence during the night Sleep Studies would not conflict with the Medicare guidelines of general supervision.

8. Even the Board has examined the manner in which activities have been treated by Medicare. In Re: Petition for Declaratory Statement of Karl Hempel, M.D. and Tallahassee Primary Care Associates, P.A., 22 F.A.L.R. 4343 (June 23, 2000), the Board reviewed how Medicare handled the billing of the technical and professional component of diagnostic imaging services. In this case, the Board agreed with the petitioner's legal analysis that "Medicare traditionally separated these two distinct aspects of the diagnostic process. Had the Florida Legislature meant to combine them together, it would have said so. Because it did not, it is logical and legally correct to conclude that diagnostic imaging services only refer to the technical component. There is no reason for concluding otherwise and there is no public policy reason for combining and confusing those two distinct services." A copy of the petition and declaratory statement is attached hereto as Exhibit H.

9. Although, Sleep Studies are not subject to the Stark Law, we believe that the Stark Law is relevant to the discussion of "direct" supervision. The Centers for Medicare and Medicaid Services ("CMS") published a commentary to the Stark Law which includes comments submitted from interested individuals and CMS' responses to them ("Stark Commentary"). This Stark Commentary, although non-binding, often provides insight as to how CMS might be expected to apply the law to certain situations, and clarification of provisions and terms of the law. In the 2001 Stark Commentary, CMS stated in relevant part:

We revisited the direct supervision requirement and are now interpreting "directly supervised" in the statute to mean that the supervision meets the supervision requirements under applicable Medicare and Medicaid payment or coverage rules for specific services at issue. Upon further review and consideration, we concluded that the Congress did not use the phrase "directly supervised" in any technical sense. Rather, the Congress sought to establish a nexus between the referring physician and the individual performing the ancillary services in order to limit the exception to services that are truly "ancillary" to the referring physician's medical practice. We believe that the Congress did not intend section 1877 of the Act to supersede or replicate existing statutory and regulatory structures that address supervision of services from the perspective of quality of care or patient safety.

This interpretation is consistent with the often cited legislative history for section 1877 of the Act indicating that the Congress did not intend to require physicians to be present at all times that ancillary services were being performed. Instead, we believe a sensible approach is to defer to existing Medicare and Medicaid supervision requirements.

66 Fed. Reg. 885 (Jan. 4, 2001) (emphasis added). See Exhibit F.

10. It is important to note that Congress did not intend to require physicians to be present at all times that ancillary services were being performed and, as such, the requirement of direct supervision was abandoned and CMS adopted the existing supervision standard under applicable Medicare and Medicaid coverage or payment rules for the specific designated health service. If a Sleep Study was a designated health service, then the Stark Law would only require general supervision of the testing.

11. Another authority for the level of physician supervision required for a Sleep Study is the American Academy of Sleep Medicine ("AASM"). AASM is the national accrediting body for sleep disorders centers and laboratories for sleep related breathing disorders. AASM accreditation is considered the gold standard by which the medical community and the public can evaluate sleep medicine services. The AASM Standards for Accreditation ensure that sleep medicine providers display and maintain proficiency in areas such as testing procedures and policies, patient safety and follow-up, and physician and staff training (the "AASM Standards"). Like Medicare, the AASM Standards only require a physician provide "general" supervision of Sleep Studies. A copy of the AASM Standards for Accreditation is attached hereto as Exhibit I.

12. In addition to the Medicare guidelines and the AASM Standards, the established community standard for physician supervision of Sleep Studies throughout Florida and nationwide is only "general" supervision. To our knowledge, there are no sleep centers, in Florida or anywhere in our country, have a physician spend the night to supervise the testing.

13. At the time the Self-Referral Act was implemented, the clinical importance of Sleep Studies was not fully realized. This is evidenced by the fact that in 1992 when the Self-Referral Act was enacted, there were only 228 accredited sleep centers nationwide. Today there are 1297 with only 50 in Florida. If the Self-Referral Act was enacted today rather than in 1992, we believe that Sleep Studies would have been specifically exempted from the definition of "referral." The fact that Sleep Studies was not listed as a designated health service suggests that the subject was never raised.

14. Currently Sleep Studies are performed in hospitals, independent diagnostic testing facilities ("IDTF"), health care clinics and physician-owned sleep centers. Locally, there is a wait time of often one month to have a Sleep Study performed in

Jacksonville, Florida. This backlog results in delay in diagnosis and treatment of sleep disorders. A delay in diagnosis and treatment can adversely impact the patient's medical condition. By having its own Sleep Center, Jax Heart could provide quicker access for its patients to testing and subsequent treatment.

15. In addition, other non-physician owned sleep centers provide diagnostic testing, but poor follow-up care. A follow-up rate of ten percent (10%) is unacceptable and does not comply with AASM Accreditation Standards which recommend follow-up care within thirty (30) days. Given that AASM accreditation is voluntary, not all sleep centers are accredited. Since Jax Heart would only perform Sleep Studies on its own patients, Jax Heart would provide continuity of care from initial evaluation through ongoing care and treatment. Moreover, most patients prefer to have tests and procedures performed at their doctor's office in an environment where they feel safe and comfortable.

16. "The Board has broad discretion and deference in interpreting a statute which it administers." Board of Podiatric Medicine v. Florida Medical Association, 779 So. 2d 658 (Fla. 1st DCA 2001). In this case, the District Court of Appeal held that the Board of Podiatric Medicine had authority to make a rule defining terms as they related to the practice of podiatry. A copy of the case is attached hereto as Exhibit J.

17. In our case, the Board possesses special knowledge and expertise regarding the clinical and practical aspects of the practice of medicine. Therefore, the Board has the authority to interpret and define terms in the Self-Referral Act.

18. In summary, the Board has broad discretion in interpreting the Self-Referral Act. Medicare regulations and accreditation standards adopted by the American Academy of Sleep Medicine require only general supervision of Sleep Studies. Sleep centers throughout Florida (and throughout the country) do not have a physician present while Sleep Studies are performed at night, even in physician-owned sleep centers. The Sleep Center proposed by Jax Heart would serve the needs of its patients and contain safeguards to satisfy the Florida Legislature's concerns regarding a potential conflict of interest inherent in a physician-owned sleep center.

VI. Relief Sought.

We respectfully request the Board interpret the Self-Referral Act to allow Jax Heart to establish the Sleep Center as a part of its medical practice. We believe Jax Heart's Sleep Center would be operated with sufficient safeguards to protect the citizens of Florida from unnecessary and costly health care.

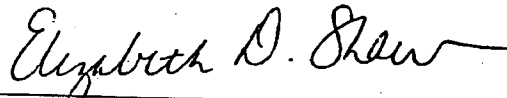
As evidenced by the allowance for absences that do not conflict with Medicare supervision requirements, the Florida Legislature did not intend for a physician to be present at all times that the health care services are performed. A Sleep Study is a very safe, non-invasive test that is generally performed at night and without a physician present. There has not been any interpretation of the Self-Referral Act with respect to physician absences at night. Clearly, a

physician's absence at night while a Sleep Study is performed is not incompatible with the current standard of care.

The supervision provided in the proposed arrangement is consistent with the Stark Law, Medicare guidelines and the established nationwide standard of care. In addition, Jax Heart has included sufficient safeguards (not provided in other sleep centers) to prevent unnecessary and costly health care expenditures. Jax Heart's implementation of the specific safeguards would address all the Florida Legislature's concerns and provide a higher level of quality for its patients. Thus the proposed arrangement should be deemed to be compliant with the intent of the Self-Referral Act.

WHEREFORE, the Petitioners respectfully request the Board to grant this Petition and issue a Declaratory Statement that the proposed arrangement would not constitute prohibited activity under Section 456.053, Florida Statutes (the "Patient Self-Referral Act of 1992").

Respectfully submitted this 6th day of September, 2007.



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