April 17, 2001

VIA COURIER

Health Care Financing Administration
U.S. Department of Health and Human Services
Attn: HCFA-1809-FC
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: HCFA-1809-FC

Dear Sir or Madam:

The American Lithotripsy Society (the "ALS") appreciates the opportunity to submit the following comments concerning "Phase 1" of the Final Rule With Comment Period (the "Regulations") implementing paragraphs (a), (b), and (h) of § 1877 of the Social Security Act, the federal physician self-referral law ("Stark II"), published at 66 Fed. Reg. 856 (Jan. 4, 2001).

The ALS, the primary spokesman for lithotripsy providers in the United States, is a not-for-profit voluntary membership organization dedicated to addressing extra-corporeal shock wave lithotripsy as a treatment modality for urinary tract stones. It represents over 2,500 physicians, lithotripsy sites and allied health professionals. The ALS and its membership are largely responsible for making lithotripsy available to patients in the United States and for making possible significant savings in health care costs.

Certain key sections of the preamble to the Regulations (the "Preamble"), including certain responses of the Health Care Financing Administration ("HCFA") to earlier comments, misstate or misinterpret Stark II, its legislative history, and the Regulations themselves. First. HCFA claims that the designated health services ("DHS") identified by Congress as "inpatient and outpatient hospital services" includes any services that a hospital provides to a hospital patient, by itself or under arrangement, notwithstanding the otherwise discrete list of specific services set forth by Congress in the Statute and the specific definitions set forth in the Regulations themselves. 66 Fed. Reg. 856, 941 (Jan 4, 2001). In particular, HCFA asserts that lithotripsy, which may only be provided to Medicare patients under arrangements with hospitals, is, for that reason, a designated health service.

Secondly, HCFA's comments with regard to the establishment of fair market value for lithotripsy are not in accordance with the express terms of Stark II. They represent an unauthorized assumption of power unilaterally to determine "reasonable rates of return." Finally, HCFA failed to comply with the Regulatory Flexibility Act, 28 U.S.C. § 604 et seq. and failed to correct earlier regulatory errors.

The impact of the policy statements set forth in the Preamble is significant. The majority of lithotripsy providers in the United States are physician-owned. Because of the draconian penalties that will attend any arrangements or activities that HCFA determines violate Stark II. implementation of the Regulations and the policy stated in the Preamble will require a massive restructuring of entities that provide lithotripsy services and the arrangements under which they provide those services.

Accordingly, we request that HCFA stay the implementation of the Regulations with

regard to lithotripsy until such time as the agency reconsiders this Rulemaking in light of these comments.

1. BACKGROUND REGARDING LITHOTRIPSY

Prior to the development of lithotripsy, patients suffering from urinary tract stones were generally forced to undergo inpatient surgical procedures to have the stones removed. Extracorporeal shock wave lithotripsy ("ESWL" or "lithotripsy") provided an alternative to that expensive and invasive treatment. Through the use of a lithotriptor, an urologist could remove stones in non-hospital settings and without invasive surgery.

Lithotripsy has been safely utilized in the United States since the mid-1980s. HCFA knows and has repeatedly acknowledged that lithotripsy may safely and efficiently be performed outside of the hospital setting. See, e.g., 56 Fed. Reg. 59502 (Nov. 25, 1991); 58 Fed. Reg. 51355 (Oct. 1, 1993); and 52 Fed. Reg. 62128 (Nov. 24, 1993).

Lithotripsy does not require a hospital setting. As a result, lithotripsy can be provided more efficiently in a stand-alone lithotripsy center, an ambulatory surgery center ("ASC"), or even in a mobile facility installed in a van. Indeed, freestanding and mobile lithotripsy facilities
are accepted and reimbursed directly by virtually all private insurance companies. Hospitals generally have not been as inclined to commit their capital resources to lithotriptor equipment or to become involved in direct leasing of lithotriptor equipment. As a result, access to lithotripsy in the United States has depended primarily on physicians obtaining lithotriptors on their own, either through ownership or lease arrangements

2. HCFA'S INTERPRETATION OF "INPATIENT AND OUTPATIENT HOSPITAL SERVICES" IS CONTRARY TO EXISTING DEFINITIONS AND IS OVERBROAD.

A. Lithotripsy is not a designated health service listed under Stark II.

Stark II was enacted into law on August 10, 1993 to control the circumstances under which a physician can refer patients to an entity in which the physician holds a financial interest. The purpose of the law is to protect patients and the Medicare Trust Fund from unnecessary medical services ordered by physicians for profit rather than good medical practice.

Stark II does not ban all referrals to entities in which the physician may have a financial interest. Stark II limits its prohibition on such referrals to eleven specific health services that Congress determined could be subject to abusive referrals. Those specific and enumerated services are identified as "designated health services," (also, "DHS").

The statute defines designated health services as any of the following items or services:

(a) Clinical laboratory services
(b) Physical therapy services
(c) Occupational therapy services
(d) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services
(e) Radiation therapy services and supplies
(f) Durable medical equipment and supplies
(g) Parenteral and enteral nutrients, equipment, and supplies
(h) Prosthetics, orthotics, and prosthetic devices and supplies

(i) Home health services
(j) Outpatient prescription drugs
(k) Inpatient and outpatient hospital services.

The law also includes within its prohibitions referrals to entities in which the physician's immediate family has a financial interest.
42 U.S.C. § 1395nn(h)(6) (2000).

B. Congress intended the term "inpatient and outpatient hospital services to have its common meaning as established by statute and regulation.

Although lithotripsy is not listed as a DHS, HCFA nonetheless asserts in the Preamble that it is a DHS anyway because Congress included "inpatient and outpatient hospital services~' as designated health services. 66 Fed. Reg. at 940. HCFA asserts in the Preamble that "inpatient and outpatient hospital services include any services that a hospital provides to a hospital patient 66 Fed. Reg. at 941 (emphasis added). ALS urges HCFA to reconsider that unsupported and expansive policy determination.

1. Inpatient hospital services

Congress did not define the term "inpatient and outpatient hospital services" in Stark II. Congress has defined "inpatient hospital services" elsewhere in the Social Security Act. In § 1861(b) of the Act, Congress stated, subject to some exclusions not pertinent here, as follows:

The term "inpatient hospital services" means the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital - -

(1) bed and board;

(2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and

(3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangement with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements.

Section 1861(b), codified at 42 U.S.C. § 1 395x(b) (2000) (emphasis added).

In earlier regulations, HCFA explained the term "certain other diagnostic or therapeutic services means services furnished by the hospital, CAH, or others under arrangements made by the hospital or CAH, billed through the hospital, and of a kind ordinarily furnished to inpatients either by the hospital or CAH or under arrangements made by the hospital or CAH." 42 C.F.R. § 409.16 (emphasis added). It is well-established that the term "ordinarily furnished to inpatients" refers to those services routinely provided to hospital patients, the costs of which ~~can be characterized as part of the hospital's expense in providing inpatient care." College Of American Pathologists v. Heckler, 734 F.2d 859, 867 (D.C. Cir. 1984). See also Hultzman v, Weinberger, 495 F.2d 1276, 1279-80 (3rd Cir. 1974) (treating such services as those associated with hospitalization).

Thus, the statutory term “inpatient hospital services” does not encompass all services rendered to persons who are inpatients of a hospital, but rather a discrete list of specific services, including routine services ordinarily furnished to inpatients. Lithotripsy is not a listed service, nor is lithotripsy a service of a kind “ordinarily furnished to inpatients.. .“ Indeed, lithotripsy need not even be performed in a hospital. HCFA itself has affirmed that no medical reason requires that lithotripsy be provided in or through a hospital. 63 Fed. Reg. 32290, 32315 (June 12, 1998) (proposing to set a reimbursement rate for lithotripsy in the Prospective Payment System for ASCS). However, HCFA continues not to reimburse lithotripsy unless the procedure is billed under an arrangement with a hospital.

2. Outpatient hospital services

Congress likewise did not define “outpatient hospital services” when it passed Stark II. In the Regulations, HCFA defined this term by reference to §§ 1861(s)(2)(B) and (C) of the Social Security Act. According to those sections, certain “medical and other health services” include:

(B) hospital services incident to physician’s services rendered to outpatients and partial hospitalization services incident to such services;

(C) diagnostic services.

Sections 1861(s)(2)(B) and (C), codified at 42 U.S.C. § 1395x(s)(2)(B) and (C). Lithotripsy does not fall within that statutory definition, and therefore does not fall within the regulatory definition.

The term “incident to” has a well-developed definition. To be covered under Medicare Part B, services “incident to” physician services must be... commonly rendered without charge or included in the physicians bill.” 42 C.F.R. § 410.26(a) (2000); MEDICARE CARRIERS MANUAL § 2050 (HCFA PUB. 14-3). Such services would include the tongue depressor used by the doctor, the nursing services supporting the doctor, and similar expenses. HCFA reimburses services incident to” physician services for hospital outpatients, and those “incident to” such physician’s services furnished by or under arrangement with a hospital. 42 C.F.R. § 410.27(a) (2000).

Lithotripsy is not a diagnostic service. Further, it is not a service provided “incident to’ physician services. It is a separate, technical service, billed separately from professional fees. HCFA nevertheless states it “would consider all covered services (either diagnostic or therapeutic) performed on hospital outpatients that are billed by the hospital to Medicare (including arranged for services) as outpatient hospital services. Id.

C. Congress did not authorize HCFA to expand the list of designated health services.

HCFA has no statutory authority to expand the scope of designated health services through the guise of regulatory definitions. Congress structured Stark II by setting forth a general prohibition on physician referrals for specific designated health services to entities in which the physician has a financial interest. Congress provided a number of exceptions to the general prohibition on referrals, including exceptions for certain group practices, for leases, and for compensation arrangements based upon “fair market value.” Congress also authorized HCFA to create “other permissible exceptions” that HCFA determines do not pose a risk of program or patient abuse. Section 1 877(b)(4), codified at 42 U.S.C. § 1 395nn(b)(4). By contrast, Congress did not give HCFA authority to expand the list of DHS.

1. The group practice exception does not justify HCFA 's expansion

HCFA further does not have the inherent authority to ignore statutory limits and create its own meaning of statutory phrases. See, e.g. Southern California Edison Company v. Federal Energy Regulatory Commission, 195 F.3d 17, 27 (D.C. Cir. 1999). Instead, the agency must defer to the plain meaning of the statutory term in the context of the statute as a whole. Id at 22.

HCFA claims that its sweeping interpretation of "inpatient and outpatient hospital services is consistent with § 1 877(e)(7) of the Act, which provides a limited exception for certain group practice arrangements with a hospital. 66 Fed. Reg. at 942; 42 U.S.C. § I 395nn(e)(7) (2000). That exception covers such arrangements for certain services existing before 1989, hence providing a "grandfather provision" for such arrangements. HCFA apparently reasons that because Congress deemed an exception to be necessary for certain services provided "under arrangement," Congress intended any other service provided to a hospital patient under arrangement to fall within the meaning of the term "inpatient and outpatient hospital services." That reasoning is flawed.

The grandfather provision did not address any service, as HCFA implies. It specifically applied only to specific group arrangements that are:

between a hospital and a group under which designated health services are provided by the group but are billed by the hospital if--

(i) with respect to services provided to an inpatient of the hospital. the arrangement is pursuant to the provision of inpatient hospital services under section 1395x(b)(3) of this title,

(ii) [the arrangement meets certain longevity requirements],

(iii) with respect to the designated health services covered under the arrangement, substantially all of such services furnished to the patients of the hospital are furnished by the group under the arrangement,

[and additional requirements]

42 U.S.C. § 1395nn(e)(7).

One of the fundamental rules of statutory construction is that every word in a statute must be given effect. See, e.g., SUTHERLAND STAT. CONST. § 46.06 (5th ed.). If, as HCFA states in the Preamble, any service provided under arrangement is a designated health service, the use of the term "designated health services" in the exception would be redundant and meaningless. If Congress had intended all services provided under arrangement with a hospital to be designated health services, it would not have said "designated health services" in the introductory clause of the section; it would not have said "pursuant to the provision of inpatient hospital services" in subsection (i), and it would not have said "with respect to the designated health services covered under the arrangement.. ." in subsection (iii).

Thus, the structure of the exception shows that Congress was not creating an exception for services under arrangement. Instead, it was providing an exception for

radiological services that otherwise would be a designated health service. The group practice exception accordingly does not support the expansive interpretation set forth by HCFA in the Preamble; it flatly refutes it.

Further corroboration comes from an analysis of how the group practice exception arose. The version of the Stark II law that was considered by the Senate contained a new subsection (e)(7) for group practice arrangements with hospitals. The version contained the identical introductory material quoted above from what is now law at 42 U.S.C. § I 395nn(e)(7). See S.1134, 103rd Cong., § 7304 (1993) at 257, line 18 to 259 , line 14, Attachment 9; see also H. Conf. Rep. No. 213, 103rd Cong., 1st Sess., 813 (1993), Attachment 10. in the Senate bill. however, the category of inpatient and outpatient hospital services was not listed as a designated health service. See 103"' Cong., § 7304 at p. 249, lines 1-15, Attachment 9. The group practice exception thus predated the inclusion of "inpatient and outpatient services" as the 11th and final designated health service.

HCFA thus cannot claim that Congress created the group practice provision as an exception to an otherwise broad definition of "inpatient and outpatient hospital services." The exception instead was intended to exclude group practices that referred patients for designated health services (in this case radiology) under arrangement with a hospital.

D. Congress Did Not Intend Lithotripsy to Be Included in the Definition of Inpatient and Outpatient Hospital Services

The above analysis of the relevant statutory provisions demonstrates that HCFA has no authority to define "inpatient and outpatient hospital services" expansively to encompass lithotripsy. The legislative history confirms that Congress never intended that lithotripsy be included in the definition of "inpatient and outpatient hospital services." In earlier comments, ALS set forth the relevant legislative history. Perhaps the most astounding aspect of the Preamble is the extent to which HCFA has distorted that history. HCFA asserts that

we believe that lithotripsy was meant to be a "designated health service" under the law, since the law does not exclude any particular hospital services, nor does the legislative history indicate that the Congress meant to exclude them. . . . In adding hospital services to the list of DHS, the legislative history reveals that the Congress was concerned about increased admissions to hospitals, regardless of the reason for the admission.

The conclusion that "lithotripsy was meant to be a 'designated health service"' does not follow from the fact that the law did not exclude it. To the contrary, HCFA's conclusion reflects a view of Stark II that was expressly rejected by Congress, when it decided against a legislative approach based upon prohibitions on referrals for all health services in favor of an approach targeted only to a few specifically identified services. Moreover, the legislative history establishes that Congress intended that lithotripsy provided under arrangement was not to be considered an inpatient or outpatient hospital service.

A recapping of some of the relevant history is warranted. Beginning in 1989 and ending in December 1993, Congress held hearings and had numerous discussions with industry representatives and policy makers concerning the issue of physician referrals. The original legislation, proposed first in 1989 and again in 1993, was extremely broad. That legislation would have prohibited a physician from referring patients for any health care service to an entity with which the physician had a financial relationship, except for those expressly exempted.

HCFA makes much of the fact that an early version of Stark I included an exemption for lithotripsy but the exception did not apply to the hospital services and was not enacted. 66 Fed. Reg. at 941. This argument borders on the disingenuous. First, hospital services were never expressly included within the scope of Stark I. Second, the lithotripsy exemption was not enacted because it was not needed. Stark I as ultimately enacted contained a much narrower scope than originally proposed. Rather than covering all referrals of all medical services to entities with which the physician had a financial relationship, it covered only referrals for clinical lab services. Since the prohibition did not extend to lithotripsy, there was no need for exemption for lithotripsy. An express exemption would have been superfluous.

In 1993, Congress again considered an amendment to Stark I that would ban physician self-referral for any health care service with certain specified exceptions. Congress ultimately took a different approach. Rather than impose a general prohibition, with specific exceptions. Congress chose to prohibit only those medical services believed to pose a risk of overutilization or patient abuse. Lithotripsy was not included as one of those services.

HCFA mentions, but fails to address, the key aspect of the legislative history of Stark II. Towards the end of the legislative deliberations, Congress added “inpatient and outpatient hospital services” as the 11 and final designated health service. While HCFA claims, without citation to any authority, that Congress was concerned over increased hospital admissions, 66 Fed. Reg. at 941, HCFA cannot point to any evidence that admissions for lithotripsy were a concern. Congress certainly did not voice any such concerns.

A concern that was stated by Congress was that HCFA might seek to add lithotripsy to the list of DHS through an expansive reading of the term “inpatient and outpatient hospital services.” During debate on the House floor regarding Stark II, Chairman Rose put the question point-blank to the legislation’s author and principal sponsor, Rep. Stark:

Mr. Rose: .. .Mr. Speaker, I ask the chairman [of the Subcommittee on Health of the Committee on Ways and Means, Rep. Stark] this question: In Section 1877 (42 U.S.C. 1 395nn(h)(6)(k)[)] the physician self-referral ban enumerates “inpatient and outpatient hospital services.” It is my understanding that this provision is not intended to apply to physician owned lithotripsy facilities that furnish services under contract with a hospital. Is this correct?

Mr. Stark: Mr. Speaker, the gentleman is correct.

Mr. Rose: Mr. Speaker, I thank the gentleman for his response.

139 Cong. Rec. H6238 (Aug. 5, 1993) (emphasis added).

Rep. Stark confirmed that lithotripsy was not intended to be considered as a DHS in a subsequent letter to Congressman Rose. In his letter December 5, 1994, he stated:

As you correctly indicate, we have discussed this issue on a number of occasions, and as indicated in our discussion reprinted in the Congressional Record, Section 1877 was not intended to prohibit the situation... where a limited partnership is created to own and operate mobile lithotripsy equipment . . . I want to re-affirm that nothing in Section 1877 was intended to prohibit referrals by the urologists for services to be provided on this equipment. Nor was that section intended to prohibit billing either Medicare or Medicaid by

the hospital for the technical component, or by the physician for the professional component of the services provided to the patients.

Other members of Congress agreed with Stark regarding lithotripsy services, including Senator Connie Mack (R-Fla.). As Sen. Mack noted in a letter dated March 3, 1998: “1 am sensitive to the concerns raised by urologists that lithotriptors be exempt from the Stark It Physician Self Referral Ban because this service is a continuation of care and an extension of the physician’s office practice.”

HCFA has made no attempt to square its interpretation of Stark II with this conclusive evidence of contrary legislative intent.

3. HCFA’S STATED REASONS FOR IDENTIFYING LITHOTRIPSY AS A DHS ARE PRETEXTUAL

Underscoring our concern over the reasonableness of HCFA’s position is the flimsiness of the justification proffered by HCFA for overriding congressional intent and including lithotripsy as a designated health service. In the Preamble, HCFA claims that it has “learned of situations in which urologists in a particular geographic area.., require that outpatient departments use the physicians’ equipment if they want to receive any urology referrals.” 63 Fed. Reg. 1683 (Jan. 9, 1998). HCFA has failed, however, to provide any evidence of these alleged situations. Indeed, HCFA has ignored, for over three years, requests under the Freedom of Information Act (“FOIA”) for such evidence. Accordingly, we can only conclude that no such information or support exists.

2 The ALS submitted a FOJA request for the information to which HCFA alludes on December 12, 1997. HCFA has not provided any substantive response.

4. PHYSICIAN-OWNED LITHOTRIPTERS DO NOT PROVIDE A POTENTIAL FOR ABUSE OR OVERUTILIZATION

Even if HCFA had the authority to adopt an expansive definition of “inpatient and outpatient hospital services that encompassed lithotripsy, we believe HCFA should also exercise its unchallenged authority to create an exception for lithotripsy. Stark II gives HCFA the power to create limited exceptions for services it believes would otherwise be DHS, where HCFA believes that an exception poses a limited risk of abuse and is necessary to avoid needless disruption in patient care.

Lithotripsy has been proven to present no risk of abuse. In June 1988, Congress directed the Office of Inspector General of the Department of Health and Human Services to conduct a study of certain physician owned services to determine whether such ownership resulted in overutilization or patient or program abuse. That study, Financial Arrangements Between Physicians and Health Care Businesses, was released by the OIG in May 1989, during the congressional consideration of Stark I. This study was limited, and covered independent clinical and pathological laboratories and durable medical equipment suppliers. In the absence of data justifying a broader ban, Congress passed Stark I, which applied to clinical laboratory services only.

Congress delayed consideration of broader application of the law in anticipation of the Florida Health Care Cost Containment Board (“the Board”) study on physician joint ventures. the most comprehensive study to date of referrals by physician owners. In fact, the Preamble references the Florida study as the basis for determining a need for the Stark II law. Similarly, the Florida legislature used that study as its basis for enacting a broad ban in

Florida on physician self-referrals for certain “designated health services” and for restricting physician ownership of all other types of health care facilities. FLA. STAT. ch. 455 (1992). That Florida law remains the most comprehensive state law banning physician self-referrals.

After considering the results of the Board’s study, the Florida legislature decided to specifically exempt certain services from the scope of the legislation. FLA. STAT. § 455.236. Lithotripsy was one of the excepted services. It was exempted because the Florida legislators found, based on the study and other considerations, that lithotripsy does not pose a potential for over-utilization or patient abuse.

Congress looked to the Florida study and the legislature’s findings in drafting Stark II. See 1992 Comprehensive Oversight Initiative of the Committee on Ways and Means, H. Rpt. 103-7; and, 1991 Comprehensive Oversight Initiative of the Committee on Ways and Means, H. Rpt. 102-431. See also Comments of Rep. Fortney Stark, March 7, 1995, 141 Cong. Rec. E.534 (Mar. 7, 1995); Comments of Senator Brock Adams on behalf of himself and Senators Jeff Bingaman and Howard Metzenbaum, August 12, 1992, 138 Cong. Rec. S12615 (Aug 12, 1992). Statements made during congressional deliberations show that the animating concern behind the legislation was the potential for physicians to make unnecessary referrals for the sake of profits and to “over-utilize” certain medical services. In particular, Congress focused on over-utilization of magnetic resonance imaging (“MRI”) services and other diagnostic services. See, e.g.. Comments by Senator Jeff Bingaman, on behalf of himself and Senator Howard Metzenbaum on Jan. 5. 1993, 139 Cong. Rec. 5 1443, (Feb. 4, 1993). Congressman Stark has stated that Stark II is based upon and largely mirrors the Florida law. Indeed, Stark II does not list as “designated health services” any of those services that are specifically exempt under Florida law, including. for example, lithotripsy. ambulatory surgery, and cardiac catheterization services.

HCFA acknowledges that lithotripsy does not present any potential for over-utilization. For example, in the preamble to the proposed regulations on Stark II, HCFA stated:

Only when a patient requires surgical treatment would a physician prescribe ESWL. When a patient needs additional treatment, there is no alternative available that is less invasive or less expensive than ESWL. In addition, the procedure itself apparently documents the medical necessity to prescribe it. As we understand ESWL, the kidney stone is located, identified, and the progress of the therapy is recorded as part of the visualization process. . . . [W]e agree that it might be unlikely that physicians would over-utilize ESWL.

63 Fed. Reg. at 1682 (Jan. 9, 1998).

Having agreed that over-utilization of lithotripsy is not really a threat, HCFA nevertheless seeks to justify’ its expansive policy by speculating that physician leasing of lithotripters to hospitals might lead to overutilization of other medical services. Specifically. HCFA contended that “there is a substantial potential ... for the financial arrangement between the lessor urologists and the lessee hospital to encourage over-utilization of other hospital services.” 66 Fed. Reg. at 940. HCFA cites no evidence supporting that speculation. Moreover. HCFA never identifies what other services might be overutilized.

5. THE RELIEF SOUGHT BY THE ALS IS NOT ILLUSORY

HCFA has reacted to a request for an express exemption for lithotripsy by claiming that the inclusion of lithotripsy in “inpatient and outpatient hospital services” does not result in any actual harm to urologists. HCFA further has stated that the relief from an exemption would be “illusory.” Specifically, HCFA claims:

In any event, the exclusion of lithotripsy from the definition of inpatient and outpatient services would not obviate the need for the physician-owners to structure their rental arrangements to comply with section 1877 of the Act.

Whether lithotripsy is a designated health service or not, the rental arrangement itself would create a financial relationship between the physician-owners and the hospital. Unless the financial relationship (that is, the lithotriptor lease) fit into a compensation exception (such as the equipment rental exception), the physicians could not refer any Medicare patients to the hospital for any inpatient or outpatient services. In short, the relief sought by these commenters would be illusory.

66 Fed. Reg. at 940. The relief sought is not illusory.

HCFA appears to be saying that even if lithotripsy were not a designated health service. urologists still could not refer patients to hospitals with which they have a financial relationship for the provision of other designated health services, including outpatient and inpatient services. unless the overall financial arrangement complies with Stark II. HCFA's position presumes. however, that lithotripsy providers have financial relationships with hospitals within the meaning of Stark II. Typically no such relationships would exist absent HCFA's unjustified interpretation of inpatient and outpatient hospital services. To the extent that there would be an indirect relationship, any compensation paid to lithotripsy providers does not vary with the volume or value of referrals. Moreover, many lithotripsy providers often perform lithotripsy at hospitals at which they have no admitting privileges, thus there is no financial relationship of any type.

6. HCFA'S INTERPRETATION OF FAIR MARKET VALUE IS WITHOUT FOUNDATION

A. Congress Did Not Give HCFA Authority to Look Beyond the Marketplace

The final aspect of the Preamble raising concerns regarding the reasonableness of HCFA's position is with respect to the definition of fair market value. Congress defined "fair market value" as "the value in arms length transactions, consistent with the general market value 42 U.S.C. § 1 395nn(h)(3). HCFA has indicated in the Preamble, however, that it wants to ignore the marketplace and make an assessment of fair market value based on what it believes to be an appropriate rate of return. HCFA justifies this deviation on the basis that "the prevalence of physician ownership of lithotripters may distort pricing in the marketplace." 66 Fed. Reg. at 941. HCFA elsewhere clarifies that it believes this "distortion" comes from lithotripsy providers having a superior bargaining position in negotiations with hospitals. See id at 940 (HCFA expressing concern over the possibility of physician-owned lithotripsy facilities "extracting higher than market rate rents for their equipment" from hospitals).

Under Stark II. HCFA has no authority to determine whether the marketplace is functioning the way HCFA would prefer or whether "distortions" have occurred. Congress has defined fair market value by reference to what is paid in arms length negotiations rather than by reference to costs and rates of return as it did in the ASC context. Nowhere did Congress give HCFA the authority to analyze costs and rates of return. Moreover, nowhere did Congress give HCFA the power to analyze the performance of the marketplace. Indeed, HCFA has not shown that it has the economic expertise to undertake such an analysis.

HCFA also has failed, once again, to supply any evidence that hospitals and

lithotripsy providers do not negotiate on an arms-length basis. The mere fact that most lithotripters are supplied by urologists or lithotripsy centers does not indicate an unequal bargaining position. Hospitals have alternatives. Hospitals in many areas may, if they choose, lease lithotripters directly from manufacturers on the same terms that urologists lease such equipment. That hospitals may decline to do so does not reflect a distortion in the market rate rents, but rather a recognition that the costs and risks of acquiring and maintaining a lithotripter are high.

HCFA also ignores the reality that if any "distortion" exists, it was created by HCFA. Because HCFA will pay for lithotripsy only if performed under arrangement with a hospital. hospitals have a bargaining position disproportionate to the little work they actually do. Because of HCFA's requirement that lithotripsy must be billed under arrangement with the hospital. the lithotripsy providers need the hospitals more than the hospitals need the lithotripsy providers.

One must also wonder why HCFA even perceives a need to decide whether the amount hospitals are willing to pay lithotripsy providers for technical fees is the result of an arms-length process. The amount paid for lithotripsy for Medicare patients is subject to a fixed HOPPS rate set by HCFA. HCFA presumably set the rate at an amount equal to (or less than) fair market value for the technical services. Thus, even if lithotripsy providers received 100% of the fee. their income would not exceed fair market value. HCFA accordingly has no valid interest in determining how hospitals and lithotripsy providers divide the technical fees. Far from ensuring the payment of fair market value, the only effect HCFA's comments will have is to shift lithotripsy revenues unfairly from the providers who perform the service to the hospital whose main function is as a billing agent.

B. Congress Did Not Give HCFA Authority to Set Limits on Rates of Return

Even if HCFA had the authority to ignore the marketplace and make its own unilateral determination of fair market value, the factors it proposes to utilize are inappropriate. HCFA notes that in situations where only physician-owned equipment is available, it would look to "alternative valuation methodologies, including, but not limited to, cost plus reasonable rate of return on investment on leases of comparable medical equipment from disinterested lessors." 66 Fed. Reg. at 944. However, not only did Congress decline to give HCFA the authority to analyze costs, it nowhere gave HCFA the power to set limits on rates of return on investments by lithotripsy providers. It is also noteworthy that HCFA's comments fail to express any concern with a "reasonable rate of return" for hospitals with regard to their investment in leases of lithotriptors. If HCFA were truly concerned about preventing "distortions" in the marketplace, it would ensure that the hospitals' rate of return did not exceed that of lithotripsy providers.

7. THE RULEMAKING DID NOT COMPLY WITH THE REGULATORY FLEXIBILITY ACT

The Regulatory Flexibility Act, 28 U.S.C. § 604 et seq., mandates that an agency prepare a Final Regulatory Flexibility Analysis ("FRFA") in conjunction with the issuance of a final rule. An agency can avoid this requirement only by providing a "factual basis" for its certification "that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." HCFA claims that no final regulatory flexibility analysis was needed because "Phase I of this rulemaking will not have a significant economic impact on a substantial number of small entities...." 66 Fed. Reg. at 952. HCFA failed, however, to provide the required "factual basis" for this statement. Indeed, HCFA conceded that it lacks the data necessary to provide even a rough estimate of the number of physician practices affected. Id. at 950. Had HCFA made a proper inquiry, it would have learned that the

Regulations will have a substantial economic impact on hundreds of lithotripsy providers.

Because HCFA has violated § 605(b) of Title 28, HCFA must stay implementation of the Regulations with respect to lithotripsy until such time as HCFA complies with the law.

8. HCFA HAS IMPROPERLY REVERSED CONGRESS' DECISION REGARDING PERIODIC LEASES

Aside from the above deficiencies, the Preamble incorrectly states the requirements applicable to the rental exception to compensation arrangements set forth in § 411.357(a). The Regulation itself is identical to the statutory language. That Regulation, mirroring the statute, exempts payments for the use of office space, provided there is a rental or lease agreement set out in writing, for a term of at least one year, that the space rented does not exceed that which is reasonably needed for a legitimate business purpose, that the charges are set out in advance and are consistent with fair market value, that the charges are not based in whole or in part on referrals, and that the agreement is commercially reasonable.

The Preamble states, however, that a rental or lease agreement for access for periodic intervals of time must specify the schedule of the intervals, their precise length, and the exact rent for the intervals. Those "requirements" appear to have been drawn from the permissive terms of an anti-kickback "safe harbor" provision set forth in 42 C.F.R. § 1001.952. Given that the language of the "safe harbor" provision is almost identical to the related lease exception in Stark II, Congress obviously used the "safe harbor" provision as a model for Stark II. The key point, however, is that Congress made two notable changes when enacting Stark II: (1) deleting the term "aggregate" in describing the compensation that must be stated in advance, and (2) dropping the requirement that periodic leases state the period in advance. Under ordinary rules of statutory construction, HCFA must view those deletions as deliberate. HCFA accordingly has no authority to override congressional intent and add those provisions via a rulemaking.

9. CONCLUSION

To preclude a massive disruption of the provision of lithotripsy services in the United States, we request that HCFA stay implementation of the Regulations with respect to lithotripsy until such time as it has had the opportunity to fully consider these comments. We further request that HCFA amend and clarify the Regulations by discarding its expansive interpretation of "inpatient and outpatient hospital services" and by clarifying that lithotripsy is not a designated health service.

Finally, we ask HCFA to reconsider and withdraw its comments concerning lithotripsy service arrangements and fair market value. Those comments are inconsistent with the statute, are not commercially rational, and will wreak significant harm in the provision of lithotripsy services to all patients.

Very truly yours,

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President, American
Lithotripsy Society