Hearing Date: September 22, 2006
Hearing Time: 10:30 a.m.

SUPERIOR COURT OF WASHINGTON IN AND FOR KING COUNTY

DELOIS GIBSON, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

VIRGINIA MASON MEDICAL CENTER, a Washington nonprofit corporation,

Defendant.

The Honorable Gregory P. Canova

No. 05-2-02198-5SEA

AMICUS CURIAE BRIEF OF AMERICAN HOSPITAL ASSOCIATION IN SUPPORT OF VIRGINIA MASON'S MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

The American Hospital Association ("AHA"), on behalf of its members, submits this *amicus* brief in support of defendant, Virginia Mason Medical Center ("Virginia Mason"). The AHA, a not-for-profit association that represents 4,800 hospitals, health care systems and other health care organizations, and 35,000 individual members committed to health improvement in their communities, is the national advocate for its members on health care issues, and ensures that its members' perspectives are considered when national health care policy is developed in Congress, the courts, and by federal agencies such as the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare program.

In the AHA's view, cases such as this that examine the relative cost structures of hospital operated sites of care, such as outpatient clinics, and their freestanding counterparts should not be considered in a vacuum – as the plaintiffs appear to do here – as there are marked differences between these types of health care providers. Hospital operated sites of care, such as the

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outpatient department plaintiffs visited here, share in the responsibilities of the hospital as well as the related financial costs, which are not borne by freestanding facilities. Different branches of the government have recognized the distinctions between hospital operated sites of care and freestanding facilities, have knowingly and willingly borne a share of these costs, and have allowed Medicare beneficiaries to share the burden as well. Accordingly, the AHA respectfully requests that the Court consider the differences between hospital operated sites of care (such as an outpatient department) and freestanding facilities, and the acceptance of these differences by the Department of Health and Human Services ("HHS"), CMS, and the Congress, in connection with the defendant's motion for summary judgment.

II. ARGUMENT

A. Hospital Operated Sites of Care Have Different Cost Structures Than Freestanding Facilities Because of the Roles Hospitals Serve

Full-service hospitals, such as Virginia Mason, serve a critical and unique role in meeting the overall health and public safety needs of their communities. These hospitals are on standby to care for their communities 24 hours a day, 7 days a week. Often, care begins at a hospital's emergency department, which can treat patients at any time. This is an expanding responsibility for hospitals, as emergency department visits have increased by over 25 percent in the last decade despite reductions in the number of emergency departments.[1] Maintaining the emergency department capabilities requires staffing in many other areas of the hospital, including laboratory, radiology, pharmacy, and intensive care units. At the same time, however, emergency department patient volume varies considerably from day-to-day, so that the costs of being prepared to provide care every day and having staff on-hand must be spread across hospital operating units.

Hospitals serve as the medical safety net for their communities, caring for all patients seeking emergency care, regardless of their ability to pay. There is no other systematic means of

[1] *See* American Hospital Association, *TrendWatch Chartbook*, (Apr. 2006), available at http://www.ahapolicyforum.org/ahapolicyforum/trendwatch/chartbook2006.html.

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obtaining health care for the poor and uninsured patients. In fact, visits to emergency departments by Medicaid patients and patients without insurance grew from 1998 to 2003 by 22%.[2] The financial burden on hospitals collectively is staggering – hospitals provided $26.9 billion in uncompensated care in 2004 alone.[3]

Hospitals also are the first responders to disasters, and they serve as key focal points for a community's disaster readiness and response effort, as sites to mobilize the resources to care for the ill and injured, provide food and shelter, and coordinate relief and recovery efforts. In order to fulfill this role, hospitals need to have comprehensive community disaster plans to address a wide array of circumstances, including large-scale accidents, natural disasters, epidemics, and terrorist acts, and must have various resources at the ready (*e.g.*, back-up generators and communications systems, personal protective gear, stockpiled medical supplies).

The stand-by role of hospitals – providing access 24 hours a day, 7 days a week; meeting emergency care needs regardless of ability to pay; and being first responders to a disaster – represent an essential component of our nation's health and public safety infrastructure. However, costs for this role are borne largely by the hospitals. Communities rarely provide funding for such activities and functions. Rather, hospitals build these costs into their overall financial structure and hope to recoup these funds through revenues from providing direct patient care, including revenues from government programs, such as Medicare, and from private insurers. These unique roles and their costs distinguish and underlie the different cost structures between hospital-operated sites of care (such as hospital outpatient departments) and freestanding facilities.

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[2] *See* Centers for Disease Control and Prevention, National Ambulatory Medical Care Survey: 2003 Emergency Department Summary, available at http://www.cdc.gov/nchs/data/ad/ad358.pdf.

[3] *See* American Hospital Association, Testimony of Dr. Dan Hanlfing before the Senate Health Education, Labor and Pensions Committee (Mar. 16, 2006), available at http://www.google.com/url?sa=U&start=1&q=http://help.senate.gov/Hearings/2006_03_16/hanfling.pdf&e=9797.

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B. Medicare Rules Recognize That Hospital Cost Structures Are Different Than Those of Freestanding Facilities

From Medicare's inception, the government has recognized that hospital operated sites of care have different cost structures than freestanding facilities. This policy is known as the Medicare "provider-based" policy and it facilitates greater levels of payments from Medicare and Medicare beneficiaries for services furnished at entities that are considered "provider-based" or "hospital-based" than those sites considered to be freestanding facilities. This status was created by CMS, as the term "provider-based" does not appear in the Medicare statute. 65 Fed. Reg. 18434, 18504 (Apr. 7, 2000) (discussing the history of the policy when first finalizing regulations).[4]

1. Basis for Hospital-Based Policy

CMS has identified a number of beneficial aspects of the hospital-based policy. The agency views the policy as allowing the main provider (*e.g.*, a hospital) to achieve economies of scale by sharing overhead costs, for example, with the hospital-based entity. For instance, CMS has noted that the billing department of a main provider could accommodate the additional work of a hospital-based entity by hiring another clerk, whereas a freestanding facility would have to create its own billing department (with Medicare bearing some of that cost). 63 Fed. Reg. 47552, 47587 (Sept. 8, 1998).

In addition, CMS believes the policy promotes enhanced beneficiary access to a wider range of health care services by allowing entities that are sufficiently integrated with the hospital to be treated as part of the hospital for reimbursement purposes (*e.g.*, as a hospital outpatient department). The agency clarified this benefit in response to a 2000 report from the HHS Office of the Inspector General ("OIG"), in which CMS stated that the hospital-based policy improves

[4] For the remainder of this document, we refer to "hospital-based entities" as those hospital operated sites of care such as outpatient departments that satisfy the requirements of the CMS provider-based policy. While the CMS policy uses the term "provider-based," since this case involves hospitals, we use the term "hospital-based" herein. Sites of care that do not meet the requirements of the CMS policy are referred to as "freestanding facilities."

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access to care because of the greater scope of services a hospital outpatient department, for example, can provide compared to freestanding facilities.[5]

2. Satisfying the Hospital-Based Criteria Imposes Financial Burdens

CMS regulations set forth detailed requirements that must be met for an entity to be considered hospital-based.[6] The regulations require that hospital-based entities such as those operated by Virginia Mason operate under the same license as the main provider (the hospital, here). 42 C.F.R. § 413.65(d)(1). While hospital licensure requirements vary by state, most states have requirements that the hospital (and the operations functioning under its license) must meet to obtain and maintain licensure. For example, states typically require that all operations functioning under the hospital license meet standards (*e.g.*, Life Safety Code, credentialing physicians, quality assurance programs) that are not required of freestanding facilities, and compliance with which consumes resources for the hospital-based entity.

In order to achieve hospital-based status, the clinical services of the entity and the main hospital must be integrated by virtue of having (i) the hospital monitor and oversee the services, (ii) the entity's medical director report to the hospital's chief medical officer, and (iii) the entity's medical records integrated with the hospital's records. 42 C.F.R. § 413.65(d)(2). Since the hospital-based entity has reporting obligations to the chief executive officer and chief medical officer of the hospital and the individuals have duties relating to the hospital-based entity, the entity must bear costs connected to the time taken by such individuals in providing the requisite oversight.

Similarly, the financial operations of a hospital-based entity such as those operated by Virginia Mason must be fully integrated within the main hospital's financial system. This

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[5] *See* Letter from Nancy-Ann Min Deparle, Administrator, to June Gibbs Brown, Inspector General (Jul. 19, 2000) (responding to an OIG report entitled "HCFA Management of Provider-Based Reimbursement to Hospitals"). The letter and the report are available at http://oig.hhs.gov/oei/reports/oei-04-97-00090.pdf.

[6] *See* 42 C.F.R. § 413.65. While the regulations contain different requirements for different types of hospital-based entities, this document discusses some, although not all, of the requirements applicable to the entities operated by Virginia Mason.

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integration is reflected by shared income and expenses between the entity and the hospital, and the inclusion of costs of the entity in the hospital's trial balance and cost reports. 42 C.F.R. § 413.65(d)(3). Since these additional accounting functions relate to the hospital-based entity, it must bear some of the costs of these functions. Most freestanding facilities, however, are not required to submit Medicare cost reports.

In addition, the hospital-based entity must comply with Medicare rules providing access to emergency care for all. 42 C.F.R. § 413.65(g)(1). For individuals who may need emergency care or who are in labor, hospital-based entities (including those operated by Virginia Mason) must provide an appropriate screening examination and stabilizing treatment if needed; post notices regarding patient rights regarding examination and treatment of such patients; and maintain records on transfers for at least five years. Staff at hospital-based entities must be trained and kept current on the examination and treatment requirements. Likewise, the hospital-based entity incurs the costs of the notices that must be posted and the costs of maintaining the necessary records for five years. None of these obligations – or the associated costs – apply to freestanding facilities.

Further, a hospital-based entity must comply with all terms of the hospital's provider agreement and must meet all applicable hospital health and safety rules in Medicare regulations in 42 C.F.R., Part 482. 42 C.F.R. §§ 413.65(g)(3), (g)(8). Together, these requirements impose considerable financial burdens on hospital-based entities that are not imposed on most freestanding facilities, such as:

- Implementing a hospital-wide quality assurance and training program;
- Including a complete history and physical workup in the chart of every patient before surgery (except in emergencies);
- Ensuring that operating room staff are supervised by an experienced nurse or physician;
- Informing each patient (or representative) of the patient's rights in advance of furnishing care;

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- Having an individual qualified to administer anesthesia perform a pre-anesthesia evaluation within 48 hours prior to surgery;
- Including in the medical staff an infection control officer who develops and implements policies governing infections and communicable diseases; and
- Developing and maintaining a system for identifying, reporting, investigating and controlling infections and communicable diseases.

C. The Government Has Known the Impact of the Hospital-Based Policy on Medicare Payments and Beneficiary Liability

As explained above, hospital-based entities such as hospital outpatient departments share in the overall costs of hospitals in meeting the health care needs of their communities and bear the costs of compliance with the CMS hospital-based policy – costs that freestanding facilities do not incur. As with all costs hospitals incur, they are built into the hospital's charges for the services they provide to patients. Hospital charges for a given service must be the same regardless of whether the service is furnished at the hospital or in a hospital-based entity.

CMS, and more broadly HHS, have always understood that hospital-based entities bear increased costs and thus have greater charges compared to freestanding facilities. Indeed, the Medicare program has knowingly borne its share of these costs and allowed its beneficiaries to share in the added costs as well as the benefits hospital-based entities offer to patients. Despite many revisions to its hospital-based policy, CMS has never altered the higher Medicare payments or resulting higher beneficiary copayment obligations that flow from the policy.

Medicare instituted a prospective payment system for inpatient hospital services in 1983 that featured a single payment for a hospital stay, replacing the "reasonable cost" payment system, which paid hospitals for their reasonable costs, as determined through the Medicare cost report. As CMS has noted, with this new payment system, hospitals "realized that if they established [hospital-based entities] that were still subject to the reasonable cost principles, they would then be able to shift some of the overhead from the hospital inpatient operating costs to these" hospital-based entities, generating increased revenues. 63 Fed. Reg. at 47857.

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Although the agency conducted rulemaking each year after implementation of the inpatient prospective payment system, it was not until 15 years later that that CMS initiated a rulemaking regarding the hospital-based policy. In a 1998 proposed rule, CMS indicated that Medicare payments and resulting beneficiary copayments for the same service would generally be greater when the service is furnished in a hospital-based entity than in a freestanding facility. Notably, CMS did not propose the elimination of hospital-based status or lessening the Medicare or beneficiary liability resulting from the policy. Instead, the agency's proposal called for the creation of regulatory criteria to ensure that the right entities were qualifying for hospital-based status. 63 Fed. Reg. at 47588.

These criteria, discussed *supra* in Section II(B)(2), were finalized in 2000. In taking such action, CMS clearly understood the payment implications, both for the Medicare program and its beneficiaries, yet remained committed to the benefits of the hospital-based policy. In the agency's April 7, 2000 final rule, CMS stated that its objective in issuing specific criteria for hospital-based status is "to ensure that higher levels of Medicare payment and [related] increases in beneficiary liability for deductibles or coinsurance (which can all be associated with [hospital]-based status) are limited to situations where the [entity] is clearly and unequivocally an integral and subordinate part of the provider." 65 Fed. Reg. at 18506.

In the midst of CMS' rulemaking on its hospital-based policy, the HHS OIG issued a report entitled "Hospital Ownership of Physician Practices," which noted that beneficiaries pay two to three times more in copayments for services furnished at a hospital-based entity than a freestanding facility. The OIG noted that if an entity is being treated as hospital-based when it is not, beneficiaries are paying excess copayments. The OIG recommended that CMS eliminate hospital-based status for hospital-owned physician practices that were not located on the campus of the hospital, but did not question the copayment levels for on-campus entities that met the

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hospital-based requirements.[7] CMS' response was to safeguard against abuse by having tighter qualification standards (which it imposed through the hospital-based regulations).[8] Given that different parts of HHS recognized the implications of Medicare's hospital-based policy, having Medicare and its beneficiaries bear added costs for services being furnished at hospital-based entities was an accepted part of this policy.

D. Congress Has Assented to the Impact of the Hospital-Based Policy on Medicare Payments and Beneficiary Liability

Since CMS first proposed the hospital-based regulations in 1998, Congress has made statutory changes to the hospital-based policy, none of which altered the greater Medicare payments or beneficiary copayment obligations. Congress' decision to refine the CMS hospital-based policy – but not eliminate it – demonstrates its recognition and acceptance of the hospital-based distinction.

For instance, at the end of 2000, Congress enacted legislation that cited the Medicare hospital-based regulations and made a number of changes to CMS' implementation of its hospital-based policy, none of which altered the aforementioned payment implications of the hospital-based rules. *See* Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554 ("BIPA"), § 404, 114 Stat. 2763A-506 (Dec. 21, 2000). One change allowed entities that were recognized as hospital-based as of October 1, 2000 to continue to be hospital-based until October 1, 2002. BIPA § 404(a). Another required CMS to continue to apply certain criteria for meeting a geographic location requirement in the hospital-based regulations. BIPA § 404(b). Finally, Congress mandated that an entity that sought hospital-based status prior to a certain date would be treated as having hospital-based status until a determination was made regarding that request. BIPA § 404(c). Given that Congress was aware of the hospital-based regulations, and

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[7] Office of the Inspector General Report No. OEI-05-98-00110 (Sept. 1999) at p. 3, available at http://oig.hhs.gov/oei/reports/oei-05-98-00110.pdf.

[8] *See* Letter from Michael M. Hash, Deputy Administrator, to June Gibbs Brown, Inspector General (Jul. 28, 1999) (responding to the OIG report on hospital ownership of physician practices). This letter is available at the website identified in n. 7 *supra*.

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presumably the accompanying agency statements referenced earlier in the proposed and final rules, its decision to make only these changes to CMS policy indicates that it accepted the increased Medicare payment levels and beneficiary copayment obligations that resulted from the hospital-based policy.

The absence of any change by Congress to the beneficiary copayment levels resulting from the hospital-based policy cannot be attributed to congressional indifference on beneficiary copayment obligations. Indeed, Congress has been active in reducing beneficiary copayment obligations for hospital outpatient services. In 1997, when mandating that CMS establish a prospective payment system for hospital outpatient services, Congress wrote into the Medicare statute explicit mechanisms designed to reduce beneficiary copayment obligations for outpatient services. *See* Balanced Budget Act of 1997, Pub. L. No. 105-33 ("BBA"), § 4523(a), 111 Stat. 445 (Aug. 5, 1997). The BBA mandated that copayment levels be fixed at levels based on 1996 data until the amount equals 20% of the payment rate under the new system, and permitted hospitals to elect to reduce copayment levels on a procedure by procedure basis. Id. Two years later, Congress amended the Medicare statute to put a cap equal to the hospital inpatient deductible on a beneficiary's copayment obligation for a single outpatient procedure. *See* Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113, § 204, 113 Stat. 1501A-345 (Nov. 29, 1999). Despite this high level of interest and the agency's inclusion of the hospital-based policy in the outpatient payment system rulemaking, Congress conspicuously opted not to affect copayment levels in the context of the hospital-based policy.

Congress has also chosen to allow for greater payment to hospital-based entities compared to freestanding facilities in other contexts. In 1997, Congress created caps in Medicare payments for therapy services ($1500 per year) and specifically provided that these caps would apply when the therapy services were furnished in a freestanding facility, but would

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not apply when the therapy services were furnished in a hospital-based entity such as a hospital outpatient department. BBA § 4541.[9] Thus, Congress has knowingly sanctioned greater Medicare payment levels for hospital-based entities compared to their freestanding counterparts.

III. CONCLUSION

The community hospitals across the country serve the health care needs of their communities on a daily basis. In addition to the traditional emergency, acute care, outpatient care, and diagnostic services, they have also become part of the public health and safety network. Hospitals such as Virginia Mason and the hospital-based entities involved in this case incur substantial costs in providing these vital services. Medicare has long recognized that hospital-based entities have higher cost structures than their freestanding counterparts and the program has borne increased costs as a result. The AHA respectfully submits that these differences between hospital-based entities and freestanding facilities are important elements for the Court to consider in the instant action.

DATED this 9th day of August, 2006.

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[9] While these therapy caps, as they have come to be known, have been subject to numerous delays in implementation (*e.g.*, BIPA § 421), such delays do not impact the congressional recognition that it would be inappropriate to place caps on hospital-based provision of therapy, in contrast to the provision of therapy services in a freestanding facility.

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