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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel. KARIN BERNTSEN, Plaintiff, vs. PRIME HEALTHCARE SERVICES, INC. et al., Defendants.	Case No. CV 11-08214-PJW **BRIEF OF THE AMERICAN HOSPITAL ASSOCIATION AS AMICUS CURIAE**

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STATEMENT OF INTEREST

The American Hospital Association ("AHA") respectfully submits this brief as amicus curiae.

Founded in 1898, the AHA is the national advocacy organization for hospitals in this country. It represents more than 5,000 hospitals, health care systems, and other health care organizations, plus nearly 43,000 individual members. AHA members are committed to improving the health of the communities they serve and to helping ensure that quality healthcare is available to, and affordable for, all Americans. The AHA educates its members on health care issues and advocates in legislative, regulatory, and judicial fora to insure that their perspectives are considered in formulating and implementing health care policy.

The AHA regularly is involved in legal matters, both as amicus curiae and as litigant. Most relevant to this matter, the AHA, along with eight of its members, served as plaintiffs in litigation related to the "two-midnights" rule. S*ee Am. Hosp. Assoc. v. Sebelius*, Case No. 1:14-cv-00609 (D.D.C). The AHA also served as amicus curiae in *Bagnall v. Sebelius*, No. 3:11-cv-01702 (D. Conn.) and 13-4179-CV (2d Cir.).

The AHA has an interest in the present litigation because it has an interest in Medicare patients—in ensuring that the elderly and infirm among us have access to the benefits to which they are entitled so they receive the care they need. In this

context, this case is significant for hospitals, physicians, and patients. It is the latest in a series of attempts by qui tam relators and government auditors and attorneys to retrospectively review the medical judgments and clinical predictions that physicians make every day against an ambiguous standard that the Centers for Medicare and Medicaid Services ("CMS") has struggled unsuccessfully to refine and clarify. Contemporaneous with this period of enforcement by hindsight, patient advocates and even CMS have alerted policymakers and the AHA to a precipitous increase in observation stay admissions, an apparently related drop in the number of patients admitted for short inpatient stays, and a resulting (and troubling) decrease in patient access to post-hospitalization benefits under Medicare. To the AHA and its members, the causal relationship between enforcement activity and this observed retrenchment seems clear. Enforcement activity communicates an unwritten rule to physicians and hospitals struggling to fill the information void left by CMS: When an inpatient stay may be brief, place the patient in "observation." In the current climate, the threat of ad hoc and potentially punitive, retrospective review tips the scales of complex medical decision making toward outpatient observation status, leaving patients in a holding pattern that increases the likelihood that they will be denied the Medicare benefits available for inpatient care. Physicians, hospitals and Medicare beneficiaries need and deserve better answers. For them, the difference between inpatient care and outpatient observation can have devastating financial

consequences.

The AHA thus seeks to provide this Court with background and context about the regulatory, legal, and clinical environments in which treating physicians make admission decisions. Regardless of the outcome of this litigation on a claim-by-claim basis, the AHA and its members urge the Court, and the Department of Justice ("DOJ"), to approach short hospital stay claims with sensitivity to the difficulties and consequences hospitals, physicians, and patients face when navigating the uncertain world of Medicare's applicable coverage.

ARGUMENT

This litigation illustrates the tension between efforts to combat fraud and abuse in the Federal health care programs and the illusive standards for Medicare coverage of inpatient and observation admissions, standards hospitals and physicians struggle to interpret and apply every day. In the absence of a clear policy on when observation status is medically appropriate, different officials and agencies have taken different positions at different times. On the one hand, CMS has long insisted that outpatient observation and inpatient care are not interchangeable or appropriate for the same clinical scenario. In fact, CMS has expressed concern for the growing reliance on observation status, particularly in light of the potentially significant financial impact it can have on patients. But, on the other hand, prosecutors and auditors send the message that observation status is

an adequate alternative to inpatient admission and should be the default mode of care much more often than physicians order it, apparently whenever competing clinical factors add any degree of uncertainty to a physician's decision. With increasing frequency DOJ has questioned the propriety of inpatient admissions, asserting (with the benefit of hindsight) that predictive physician decisions were not only wrong—but fraudulent. The chilling effect that results from second guessing these decisions in the absence of an articulated standard for observation status has had a clear impact on the way Medicare patients receive care in America's hospitals.

Observation status and the incidence of longer observation stays are on the rise. One recent study, for example, found that the number of observation stays increased by 88 percent between 2006 and 2012. *June 2015 Report to the Congress: Medicare and the Health Care Delivery System*, MedPAC, 185 (June 15, 2015), *available at* http://www.medpac.gov/docs/default-source/reports/chapter-7-hospital-short-stay-policy-issues-june-2015-report-.pdf?sfvrsn=0 (hereinafter "MedPAC Report"). Although physicians strive to base inpatient admission decisions on clinical considerations, there can be no doubt that their judgments are subject to influence by the knowledge that certain decisions will be questioned by government lawyers, whistleblowers, and their experts after the fact, based only on a cold paper record.

Hospitals and physicians are left in an untenable position. When they admit patients for short inpatient stays that they reasonably deem medically necessary, they may well face the cost and burden of scrutiny by whistleblower attorneys, prosecutors, and auditors, not to mention the risk of astronomical monetary damages and severe penalties. When they defer to the apparent, albeit unstated, preferences of these overseers and order observation services instead, they face criticism from patient advocates and CMS. It has become a no win situation for those physicians attempting to provide their patients with the highest appropriate quality of care within the benefits defined for them by Medicare.

Against this backdrop, it is critical in False Claims Act ("FCA") litigation that the government specifically articulate the clinical criteria to explain why specific patients should have been placed in outpatient observation status rather than treated as inpatients *and* anchor that explanation in clear statements of coverage policy previously articulated by CMS. The AHA respectfully requests that the Court hold the government to this standard of pleading and that DOJ bear in mind the ramifications of this litigation for Medicare beneficiaries across the country. Regardless of the outcome, the medical community is watching, and is concerned about how FCA litigation like this case will affect patient care.

I. Inpatient Status and Observation Status Are Not Interchangeable.

Observation status is not a substitute for inpatient care. The Medicare statute

has never included a formal definition of observation status, or even what it means to be an "inpatient" or an "outpatient." Historically, CMS has required the treating physician to make a fact-sensitive prediction about the length of time a patient will require hospitalization and has tied the "inpatient" definition to admission itself. *See, e.g.*, Medicare Benefits Policy Manual ("MBPM"), Chap. 1, § 10. Observation is a distinct type of hospital care, which involves ongoing monitoring, testing, assessment, and reassessment solely for the purpose of determining the need to admit a patient. MBPM, Chap. 6, § 20.6; *see also id.* ("Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge.") It is different from inpatient, emergency, clinic, and recovery services, and does not substitute for or duplicate the services delivered in another setting.

CMS has long held this position. The agency does "not consider observation services and inpatient care to be the same level of care and, therefore, they would not be interchangeable and appropriate for the same clinical scenario." 72 Fed. Reg. 66580, 66814 (Nov. 27, 2007). In fact, CMS repeatedly has expressed concern about the increasing trend toward longer observation stays. *See, e.g.*, 78 Fed. Reg. 50495, 50907-08 (Aug. 19, 2013) (expressing concern because of the potential financial impact on Medicare beneficiaries).

As CMS aptly recognized in a 2010 letter to the AHA, the difference between inpatient and observation status is of practical significance for Medicare beneficiaries. *See* Letter from Marilyn Tavenner to Richard Umbdenstock (July 7, 2010) ("Observation care of more than 24 hours can have tremendous impact on Medicare beneficiaries"), *available at* http://www.fiercehealthcare.com/healthcare/centers-for-medicare-medicaid-services-letter-to-american-hospital-association-extended. Inpatient stays are covered under Medicare Part A. They are subject to a one-time deductible for all inpatient services provided during the first 60 days of a stay during an annual benefit period. *See* 78 Fed. Reg. at 50907. Beneficiaries also may be eligible for a Medicare-covered stay in a skilled nursing facility after an inpatient stay. *Id.* Beneficiaries treated under observation status, by contrast, must make coinsurance payments for every service they receive, are responsible for paying for certain "self-administered drugs" that Medicare does not cover, and are less likely to be eligible for Medicare skilled nursing facility coverage. *Id.* As such, Medicare beneficiaries who receive observation services may have to pay significantly more for an episode of care than those treated as inpatients.

On November 3, 2011, Medicare beneficiaries filed a nationwide class action, which is still pending in the United States District Court for the District of Connecticut. They argued that the Secretary's policy of allowing hospitalized

patients to be placed in observation status, rather than formally admitting them, deprives them of their Part A coverage in violation of the Medicare statute, the Administrative Procedure Act, the Freedom of Information Act, and the Due Process Clause. *See Bagnall v. Sebelius*, No. 3:11-cv-01703 (D. Conn.). They have experienced first-hand the differences between inpatient admission and observation status.

II. There Are No Clear Clinical Standards For These Admission Decisions.

The standards by which government attorneys and auditors evaluate inpatient admission decisions have changed over time, as CMS has struggled to create rules governing payment for complex medical decisions. To date, CMS has offered no clear solution. During the years relevant to this litigation, CMS asked physicians to "use a 24-hour period and the expectation of a beneficiary's need for an overnight stay in the hospital as inpatient admission benchmarks." 78 Fed. Reg. 27486, 27646 (May 10, 2013). Then, in August 2013, CMS promulgated the "two-midnights rule," providing that a Medicare beneficiary would be an "inpatient" only if the admitting physician expects that beneficiary to need care in the hospital for a period spanning two midnights—that is, when the patient was admitted on day one and stayed in the hospital that night, the next day, and the next evening until at least midnight. 78 Fed. Reg. at 50944. After a contentious notice-and-comment

rulemaking proceeding, CMS adopted an exception to allow for Medicare Part A payment on a case-by-case basis for inpatient admissions that do not meet the two-midnights standard if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care despite an expected length of stay that is less than two-midnights. *See* 80 Fed. Reg. 70298, 70538-49 (Nov. 13, 2015) (codified at 42 C.F.R. § 412.3(d)(3)).

Whether treating physicians are asked to forecast a 24-hour period, one overnight stay, or a stay covering two-midnights, the coverage rules, such as they are, require them to make a time-oriented prediction based on a wide array of patient-specific clinical factors, including "patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event." 78 Fed. Reg. at 50944. The Medicare Benefits Policy Manual lists additional considerations, including the types of facilities available, hospital by-laws and admissions policies, and the relative appropriateness of treatment in each setting. MBPM, Chap. 1, § 10.

"[G]iven the unique clinical circumstances of Medicare beneficiaries who require hospital care," CMS has declined to adopt a set of specific clinical standards for determining whether a patient should be treated on an inpatient or observation basis. 80 Fed. Reg. at 70547. It does not require or endorse any specific commercial screening tool and such tools are not binding on hospitals, CMS, or its

review contractors. *See id.* at 70541-42; *see also CMS Guidance on Hospital Inpatient Admission Decisions*, MLN Matters ® Number: SE1037 (July 31, 2012), *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/se1037.pdf. Instead, as the Medicare Payment Advisory Commission ("MedPAC")[1] recognized, "Medicare's requirements for medically necessary inpatient admissions give deference to clinicians and providers and thus are open to interpretation." MedPAC Report at 173. But room for interpretation can lead to differences in opinion. Indeed, "the difference between these [inpatient] criteria and the criteria for outpatient observation status are often unclear to providers." *Id.* at 177.

III. When Reasonable Physicians Apply Ambiguous Predictive Coverage Standards, Variable Admission Patterns Are The Predictable Result.

Predicting the length of time an elderly patient will require care in a hospital is never certain. But how could it be? A degree in medicine doesn't come with a crystal ball. Instead, highly individualized medical histories, comorbidities, present signs and symptoms, and medical judgment combine to inform rough probabilities of risk and the likelihood that a patient may need care or intervention not readily available outside of a hospital. Consequently, on a case-by-case basis, reasonable,

[1] MedPAC is a nonpartisan legislative branch agency that provides the U.S. Congress with analysis and policy advice on the Medicare program.

well-intended physicians can and do disagree about the specific length of time patients might require hospitalization.

Even government professionals draw different conclusions from similar patient records. CMS-contracted Recovery Audit Contractors ("RACs") have focused most of their attention on the same category of cases at issue in this litigation—hospital claims for short inpatient stays, retrospectively finding that the care was provided in the wrong setting. *See* American Hospital Ass'n, *Exploring the Impact of the RAC Program on Hospitals Nationwide* (hereinafter "RAC Report"), at 33-41 (Nov. 21, 2013), *available at* http://www.aha.org/content/13/13q3ractracresults.pdf. In fact, in 2012, more than 94 percent of the overpayments identified by Medicare contractors were for inpatient hospital claims. CMS, *Recovery Auditing in Medicare for Fiscal Year 2013: FY 2013 Report to Congress as Required by the Social Security Act* at 12, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/FY-2013-Report-To-Congress.pdf. But, fortunately, RAC audits are not the end of the story. The AHA found that an astonishing 67% of appealed RAC decisions are ultimately reversed in favor of the provider, showing high levels of internal disagreement about inpatient decisions in the context of retrospective diagnostic review. RAC Report at 55.

In light of these statistics, the mere fact that experts for the government reviewing medical records in a litigation context disagree with a treating physician's clinical judgment made for their patients in the course of an episode of care, does not mean that one judgment was right and the other was wrong. Medical professionals surely can come to different conclusions about predictive decisions without one engaging in fraud. AHA respectfully requests that DOJ and the Court make it clear that disagreements that underscore the complexity of clinical judgments are not, in and of themselves, badges of fraud.

IV. Heightened Enforcement Risks Have A Chilling Effect On Inpatient Admissions, Despite Concerns About Increased Use Of Long Observation Stays.

Faced with the uncertainty inherent in long-term predictions, the lack of clear guidance, and the burden of DOJ's widespread practice of second-guessing predictive judgments, the government attorneys and auditors have been sending a clear message to physicians: order outpatient observation services for as long as it takes to confirm, with certainty, that the patient requires hospitalization for the requisite period of time (now, two-midnights). This message undermines the Secretary's own stated intent to reduce the occurrence of long observation stays and her concerns about recent increases. *See* 78 Fed. Reg. at 50906-07.

As a consequence, hospitals and physicians have begun to exercise greater caution when admitting patients. Where they previously may have erred on the side

of more care for vulnerable Medicare patients, who often are quite elderly and have multiple and chronic illnesses, the added enforcement risks appear to be forcing health care providers to place beneficiaries in observation status to wait and see if it suffices. In November 2010, AHA representatives met with DOJ attorneys to express the "substantial and even devastating impact" that FCA investigations can have on its members. Letter from Richard Umbdenstock to Edward Siskel and Michael Hertz (December 7, 2010), *available at* http://www.aha.org/advocacy-issues/letter/2010/10128-lt-RU-DOJ.pdf. The investigations "can also have unintended consequences for the delivery of health care services to patients, including Medicare and Medicaid beneficiaries." *Id.*

In June 2015, MedPAC reported that between 2006 and 2012, the number of outpatient observation stays increased by 88 percent, and the number of inpatient stays preceded by observation increased by 96 percent. MedPAC Report at 185. The growth in observation was most rapid between 2011 and 2012. *Id.* The average length of outpatient observation stays also increased between 2006 and 2012, from 25.6 hours per stay to 29.3 hours per stay. *Id.* Additionally, between 2009 and 2012, the number of hospital stays that were discharged to a SNF without SNF coverage increased more than 70 percent, showing the financial impact observation status has on beneficiaries. *See id.* at 189. These numbers are significant. Because observation status is not a substitute for inpatient status, prosecutors should not

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push hospitals into using it as a default. To do so would be a disservice to Medicare beneficiaries.

V. Against This Backdrop, It Is Vital That DOJ Allege With Specificity Why Inpatient Claims Are Improper.

As law enforcement has moved more aggressively to combat fraud and abuse in government health care programs, physicians and hospitals have had to look to enforcement activity in addition to traditional sources of information to identify the standards against which their conduct and, increasingly, the practice of medicine will be judged. Because the line between observation and inpatient services is not well-defined, imprecise, unexplained allegations that observation services, rather than inpatient services, should have been provided to patients only make matters worse for the patients of well-intended physicians. As MedPAC has recognized, the difference between inpatient and outpatient observation criteria are often unclear. MedPAC Report at 177. Hospitals and physicians want to make the most clinically and legally appropriate decisions for their patients. As such, they are watching and waiting, hoping for a Court to require DOJ to offer a clearer articulation of what makes medical judgment false under the FCA.

CONCLUSION

The AHA takes no position at this time regarding the proper outcome of this case. It seeks only to provide this Court with background and context about the

1 difficulties hospitals and physicians face with respect to admission decisions. They
2 are in the middle of a tug-of-war, with patients and CMS on one end and
3
4 prosecutors and whistleblowers on the other—and no referee to explain the rules.
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7 October 25, 2016

Respectfully submitted,

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