February 6, 2019

Ms. Melinda Reid Hatton
Senior Vice President and General Counsel
American Hospital Association
800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956

Dear Ms. Hatton:

Thank you for your letter dated December 19, 2018 regarding the work of our office and specifically the report we issued in September 2018 entitled *Many Rehabilitation Facility Stays Did Not Meet Medicare Coverage and Documentation Requirements* (A-01-15-00500). We appreciate your sharing your concerns, however we believe that your letter mischaracterizes our office's work and proffers several inaccurate assertions.

The Department of Health and Human Services (HHS), Office of Inspector General (OIG), oversees HHS programs to ensure compliance with Medicare laws and regulations. This work protects the integrity of HHS programs and the health and welfare of program beneficiaries. Each year, inappropriate Medicare fee-for-service payments cost taxpayers more than $30 billion. Our reviews are a critical component of a robust oversight program designed to reduce or eliminate inappropriate Government spending. The purpose of our audit was to inform the Centers for Medicare & Medicaid Services (CMS) of the status of Inpatient Rehabilitation Facility (IRF) compliance with current Medicare coverage and documentation requirements and to make recommendations to strengthen program integrity.

In your letter, you questioned the criteria and methodology OIG applied in this report. OIG conducts audits in accordance with generally accepted government auditing standards, which require that audits be planned and performed to obtain sufficient, appropriate evidence providing a reasonable basis for OIG findings and conclusions. When conducting reviews pertaining to Medicare, we work closely with our legal counsel and CMS to ensure that we are applying criteria correctly. For this review, we selected a stratified random sample of 220 Medicare IRF claims (IRF stays) from all Medicare IRF claims that were submitted in 2013. The review found that 175 of these IRF claims did not meet the Medicare coverage and documentation requirements. Based on the results of this sample, we used standard statistical techniques to estimate that Medicare inappropriately spent $5.7 billion in 2013 for these services.

An independent medical review contractor reviewed the medical records submitted by the providers to determine whether IRF services were medically necessary and provided in accordance with Medicare requirements. We worked with the medical reviewers to ensure that they applied the correct Medicare criteria and that they used professionals with appropriate medical expertise, including physicians with training and expertise in rehabilitation. OIG did not "second-guess" the

physician's judgement who ordered the IRF service, but rather appropriately assessed the medical documentation to determine if it supported Medicare payment. Medicare requires services be appropriately documented; it also must have the ability on a post-payment basis to verify that a payment was made in accordance with its requirements.

OIG audits use sampling and extrapolation methodologies, which have been consistently upheld by administrative appeal boards and Federal courts, to estimate the loss to Medicare from misspent funds.[1] Further, this was a nation-wide review intended to inform CMS about potential issues and opportunities for strengthening IRF program integrity by looking at a broad spectrum of IRF claims. In support of this goal, it was not necessary for OIG to recommend that CMS recover overpayments from IRFs that had claims that did not meet Medicare requirements. We did request confirmatory responses from 90 of the 164 IRFs associated with our sample claims as to the completeness of their documentation and we gave them the option to provide additional documentation.

The high error rate that we identified in our review has been corroborated by other more recent IRF audits. For example, the Comprehensive Error Rate Testing Program (CERT) published in 2016 (for claims from July 1, 2014 through June 30, 2015) found that the error rate for Medicare payments to IRFs was 62 percent. Further, our results are consistent with the results of recent audits of IRFs conducted by CMS's supplemental medical review contractors and some Medicare administrative contractors that found denial rates of 80 to 100 percent. OIG is not unique in finding substantial issues with IRF claims.

Your letter incorrectly conflates an auditee's favorable appeal decision with an error in OIG's findings. Appeals and audits are two distinct processes that employ different evidence to answer different questions. We note that our reviews assess compliance with Medicare requirements that Administrative Law Judges are not strictly required to follow. Moreover, additional documentation may be made available during the appeal process that was not made available during the audit.[2] HHS has begun a number of actions to improve the appeal systems. We are also committed to improving the audit process and therefore will take steps to improve the tracking of appeals from our reports so we can use the results when planning future work.

Lastly, we disagree with your assertion that our recommendations related to legislative and regulatory changes do not recognize the recent and substantial reforms authorized by Congress and CMS. In addition to recommending ways that CMS could improve compliance monitoring, coordinate provider training, and reevaluate the IRF payment system, we identified that, as a result of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014, the IRF payment methodology may become a component of a unified post-acute-care (PAC) prospective payment system (PPS). We also recognized the efforts of the Medicare Payment Advisory Commission (MedPAC) in its response to the initial mandate of the IMPACT Act. MedPAC has recommended features of a unified PAC PPS based on patient characteristics rather than setting, a

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[1] *See e.g., Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012); *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), *adopted by* 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

[2] Again, we note that we did not recommend that CMS recover overpayments. Therefore, IRFs need not appeal the claims in our review that did not meet the Medicare coverage and documentation requirements.

closer alignment of costs and payments, more equitable payments across different kinds of patients, and outcomes-based quality measures. We also recognized CMS's additional educational outreach efforts during 2016 and 2017, including "Open Door Forums" designed to provide IRFs information and solicit their feedback pertaining to the IMPACT Act.

In conclusion, we believe that our medical reviewers applied the correct criteria pertaining to Medicare coverage of IRF services and that the statistics used in the report are accurate and used in an appropriate manner. We worked closely with CMS as we conducted this review. In response to the draft report, CMS outlined steps it was taking to address the deficiencies we identified. In addition, in written comments to our draft, CMS concurred with all of our recommendations, described actions that it planned to take to address them, and reiterated its commitment to providing Medicare beneficiaries with high-quality healthcare while preventing improper payments. We believe our report, as well as other available evidence, correctly concludes that there are significant compliance concerns with Medicare payments for IRF services. Because billions of dollars are being misspent by the Medicare Trust Fund and by taxpayers, we continue to believe that strong corrective action is warranted, including further oversight by CMS, a reevaluation of the payment system, improving the appeal process, and instituting prior authorization demonstrations to assess whether compliance can be improved without restricting access to medically necessary services.

We strive to be responsive to concerns and criticisms raised about our work and incorporate such feedback as appropriate. We have received multiple letters that you have sent to us and to CMS related to our work associated with hospitals. We have responded to your letters and met with you and members of your organization multiple times. While we appreciate your perspective, we believe that we have been clear in stating our position with respect to how these reviews have been conducted and that the results do in fact accurately show significant problems with Medicare payments. The work conducted by my office, and the specific oversight that we provide to Medicare payments to hospitals, is a critical component of a vigorous oversight program and essential to ensuring that Medicare dollars are spent in accordance with program requirements.

Sincerely,

/Gloria L. Jarmon/
Deputy Inspector General
for Audit Services

Enclosures:
A: OIG January 15, 2015 letter to Ms. Hatton
B: OIG July 29, 2016 letter to Ms. Hatton

cc:
Jennifer Main, CMS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

January 15, 2015

Melinda Reid Hatton
Senior Vice President and General Counsel
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Dear Ms. Hatton:

I am writing in response to your letter of November 20, 2014, regarding our hospital compliance reviews. We value the input we have received from you and others in the hospital industry on these issues and appreciate the opportunity to address the concerns that you have raised.

Background

The Department of Health and Human Services (Department or HHS), Office of Inspector General (OIG), has long been committed to working with the hospital and provider community to provide education and training to improve compliance with Medicare laws and regulations. The goal of this work is to protect the integrity of HHS programs and the health and welfare of program beneficiaries. To this end, we have pursued a multi-disciplinary strategy to promote compliance that includes, for example, audits and other retrospective reviews, education, and guidance products to aid providers in upfront voluntary compliance efforts. Our guidance products include compliance program guidance and advisory opinions, as well as a collection of educational materials available on our Web site at http://oig.hhs.gov/compliance/provider-compliance-training/index.asp#materials. Through public comments, roundtables, and other mechanisms, we solicit industry input about our compliance and education tools and consider feedback from a range of public and private stakeholders.

Our hospital compliance reviews are part of a broad commitment to promoting greater compliance by hospitals and health systems. Using OIG's extensive experience in hospital audits, investigations, and inspections, we identify areas at risk for noncompliance with Medicare billing requirements. We use the results of our data mining and analysis to identify hospitals that appear to be at risk for noncompliance. All of our audits are conducted in accordance with generally accepted government auditing standards, which require that audits be planned and performed so as to obtain sufficient, appropriate evidence providing a reasonable basis for OIG findings and conclusions. For every hospital compliance review that we undertake, we work closely with the Centers for Medicare & Medicaid Services (CMS), our legal counsel, and the audited entity. We make every effort to ensure that we apply criteria accurately. Because every hospital is unique, the data-driven reviews are tailored to identify and review each individual hospital's specific areas of risk.

OIG's continued review of Medicare Part A payments, which according to the Congressional Budget Office comprise about 24 percent of all Medicare payments, is essential to ensure proper expenditures of Federal funds. The Department's 2014 *Agency Financial Report* estimated improper payments in the Medicare fee-for-service program of $42.7 billion, which represents an 11.8-percent improper payment rate. A contributing factor cited by the Department for these improper payments is medical necessity errors for inpatient hospital claims, such as short-stay claims, that were determined to not be reasonable and necessary in an inpatient setting.

Response to American Hospital Association Concerns About Hospital Reviews

Your letter raised four main areas of concern about our application of Medicare rules and policies: (1) the need for a physician order, (2) the treatment of canceled surgeries, (3) the rebilling of Medicare Part A claims under Part B, and (4) the review of claims beyond the statute of limitations. We address each of these concerns below. For the reasons noted, we respectfully disagree with the American Hospital Association's (AHA) legal conclusions and characterizations.

The first concern focuses on the requirements that an inpatient admission be documented by a physician's written certification (also called an order) as to the medical necessity of the admission. OIG's application of a physician-order requirement is supported by legal authority, and OIG applied the requirement only after extensive consultations with CMS. The CMS regulation in effect during our audit periods stated that Medicare paid for inpatient hospital services only if a physician certified and recertified the reasons for continued hospitalization.[1] In its 2013 regulations regarding the physician certification requirement, CMS thoroughly discussed the history of this issue and repeatedly described the physician-order requirement as a "longstanding policy" rather than as a new requirement.[2] Accordingly, for all the claims reviewed in our hospital compliance reviews, CMS required hospitals to have a physician order authorizing the inpatient admission to properly bill for Medicare Part A services.

The second concern raised by your letter involves Medicare reimbursement for an inpatient stay for a canceled surgery. Medicare requires that a service must be reasonable and necessary to be payable.[3] During our audit periods, CMS implemented this requirement for hospitals by requiring that the admitting physician have an expectation that the patient would require a stay of 24 hours or more.[4] In addition, Medicare policy states that the admitted beneficiary "must demonstrate signs and/or symptoms severe enough to warrant the need for medical care and must

[1] 42 CFR § 424.13(a)(1)(i) (2012).

[2] See CMS's discussion in Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals, 78 Fed. Reg. 50496, 50938-50942 (Aug. 19, 2013), in which CMS states, among other things, that "our longstanding policy, as reflected in our regulations and other guidance, has been that a physician order is required for all inpatient hospital admissions, regardless of the length of stay. We believe that this policy is a legally supportable interpretation of [the Social Security Act.]"

[3] Social Security Act § 1862(a)(1)(A).

[4] Medicare Benefits Policy Manual, Pub. 100-02, ch. 1, §10.

receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis."[5] In our audit work, we found examples of canceled surgeries billed by hospitals to Medicare as inpatient stays in which a patient was admitted for a scheduled non-emergency procedure but: (1) a surgery room had been overbooked or was not available or (2) a preoperative exam before admission showed the patient no longer qualified for the procedure. Such admissions are not reasonable and necessary for the treatment of illness or injury.

The third concern pertains to offsetting (or "rebilling") Medicare Part A overpayments with amounts that may be payable under Medicare Part B. We recognize in a footnote in our hospital compliance reviews that Medicare Part B rebilling may affect the final overpayment amount. However, CMS is ultimately responsible for administering Medicare and contracts with Medicare administrative contractors to process and pay claims. OIG cannot judge the value or allowability of Part B claims that have yet to be submitted. Consequently, providing an offset to the Part A overpayment with Part B reimbursement figures is not within the scope of these OIG reviews. However, OIG has assured hospitals that we would work with CMS to determine the offset Part A overpayments should CMS determine the Part B offset is a viable option.

AHA's fourth concern relates to OIG's review of claims outside of the 4-year claims-reopening period. CMS allows for reopening of claims at any time provided that there is reliable evidence that the initial determination was procured by fraud or similar fault.[6] While some of our reviews include claims beyond the reopening period, OIG ultimately recognizes CMS as the cognizant Federal agency that has the authority to decide how to resolve these claims.

Your letter also expressed concern with our use of extrapolation in generating overpayment estimates. Each hospital review is unique; the sampling method used in each review may vary because of different risk factors. As we did more hospital compliance audits, we began the use of statistical sampling to draw conclusions about a larger portion of the hospital's claims. The use of statistical sampling in Medicare is well established and has repeatedly been upheld on administrative appeal within the Department and by Federal courts. These hospital reviews determine whether Medicare claims have been submitted in accordance with laws and regulations and if the services were reasonable and necessary. One purpose of OIG's oversight is to identify as accurately as possible the amount of overpayments received by a provider, so that those can be returned to the Medicare Trust Fund. Determining the overpayment through sampling and extrapolation, rather than reviewing each claim, is both economical and in the best interest of the provider and the Government. OIG uses a conservative method under which overpayment estimates will almost always be lower than the estimates that would result from reviewing every claim.

Conclusion

Our hospital compliance review work reflects our commitment to applying Medicare requirements correctly and, when appropriate, using a statistically valid methodology to estimate overpayments. We have solicited provider input about this work and incorporated feedback, as

[5] Medicare Program Integrity Manual, Pub. 100-08, ch. 6, § 6.5.2.

[6] 42 CFR § 405.980(b).

appropriate. The reviews have served an important role in highlighting vulnerabilities in hospital billing and returning improper payments to the Medicare Trust Fund. Additionally, these reviews are a critical component of educating providers about how to identify and remediate risk areas in billing Medicare. It is our hope that hospitals, including hospital compliance departments, will use the results of our reviews to reduce the number of billing errors in the future and to otherwise strengthen the culture of compliance at their facilities.

OIG is committed to continuing its oversight of Medicare, including hospital payments, to reduce fraud, waste, and abuse. Currently, OIG has a number of reviews in progress that include the review of compliance with short-stay requirements. These reviews assess claims submitted before the implementation of the two-midnight inpatient admission requirements effective October 1, 2013. We are completing our review of these claims for adherence to the rules that governed hospital billing at the time the services were provided. The criteria we are using in these reviews are sound. Notwithstanding, we acknowledge the dynamic landscape surrounding inpatient short stays. As a result, we have voluntarily suspended reviews of inpatient short stay claims after October 1, 2013, consistent with the moratorium placed on the recovery audit contractors. We will continue to evaluate this important issue and adjust our work accordingly.

We appreciate the opportunity to respond to the concerns that you raised in your November 20, 2014 letter, and the informative and helpful discussions we have had with representatives of your organization on these topics. We look forward to continuing productive dialogue regarding these important Medicare oversight issues.

Sincerely,

/Gloria L. Jarmon/
Deputy Inspector General for Audit Services

cc:
Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services

Deborah Taylor
Director and Chief Financial Officer
Office of Financial Management
Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

July 29, 2016

Ms. Melinda Reid Hatton
Senior Vice President and General Counsel
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Dear Ms. Hatton:

I am writing in response to your letter of May 23, 2016, regarding your concerns related to our hospital compliance reviews. We appreciated the opportunity to meet with you on June 7, 2016, along with representatives from Mount Sinai Hospital, to further discuss the issues you raised in your letter and the ongoing review at Mount Sinai.

I wanted to take this opportunity to again state our views on the issues that you have raised in your most recent letter. Many of these views were expressed in our January 15, 2015, letter to you (copy enclosed). With respect to the specific issues in your letter:

At no time have we stated that our hospital compliance audits would end soon. On the contrary, we have repeatedly stated that the magnitude of Medicare payments made to hospitals and the significant fee-for-service error rate necessitate a strong oversight role for our office. We stated in our January 15, 2015, letter that we were voluntarily suspending reviews of "short stay" inpatient services that occurred after October 1, 2013 (the implementation date for new requirements associated with the two-midnight inpatient admission requirements). We also stated that reviews in progress of claims prior to October 1, 2013, would continue.

At no time have we stated that we would discontinue the use of extrapolation with respect to estimated overpayments. On the contrary, the use of statistical sampling in Medicare to determine overpayment amounts is well established and has repeatedly been upheld on administrative appeal within the Department and by Federal courts.

We maintain that our hospital compliance reviews serve an important role in highlighting vulnerabilities in hospital billing and returning improper payments to the Medicare Trust Fund.

We appreciate the opportunity to respond to the concerns that you raised in your letter, and the informative and helpful discussions we have had with representatives of your organization on these topics.

Sincerely,

/Gloria L. Jarmon/
Deputy Inspector General
for Audit Services

Enclosure

cc:
Centers for Medicare & Medicaid Services