DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General
Washington, D.C. 20201

AUG 22 2000

Mr. Rick Pollack
Executive Vice President
American Hospital Association
325 Seventh Street, NW
Washington, DC 20004

Dear Mr. Pollack:

This is in response to your letter of August 11, 2000, seeking clarification on several issues relating to the implementation of the outpatient prospective payment system (OPPS) for hospitals. On behalf of the American Hospital Association (AHA), you requested that we review the AHA's recommendations to its members regarding (1) the repayment of overpayments related to improper OPPS claims and (2) the potential application of the Office of Inspector General's (OIG) Provider Self Disclosure Protocol.

First, with respect to the AHA's proposed guidance to its hospital members regarding the reporting of overpayments, we concur that providers should follow guidance issued by the Health Care Financing Administration (HCFA) or its contractors. Your letter referenced HCFA Transmittal No. AB-99-33. Your members should also heed any additional HCFA transmittals or guidance that may be issued on this subject in the future. As your August 11, 2000 letter further noted, the hospitals must also follow additional guidelines issued by their respective contractors (e.g., carrier or fiscal intermediary) with regard to the reporting of overpayments. I also point out that, in addition to reporting the identified overpayments, providers have the responsibility to repay expeditiously those amounts.

With regard to the application of the OIG's Provider Self Disclosure Protocol, as you correctly quoted, "[t]he Provider Self-Disclosure Protocol is intended to facilitate the resolution of only matters that, in the provider's reasonable assessment, are potentially violative of Federal criminal, civil or administrative law." Indeed, the Protocol further states that "[m]atters exclusively involving overpayments or errors that do not suggest that violations of law have occurred should be brought to the attention of the entity (e.g., a contractor such as a carrier or an intermediary) that processes claims and issues payment on behalf of the Government agency responsible for the particular Federal health care program (e.g., HCFA for matters involving Medicare)." In the case of an error relating to the outpatient prospective payment system, the provider will have to assess whether it is the result of conduct that is potentially violative of the law.

Your letter of August 11, 2000 also set forth recent developments in the implementation of OPPS that are of concern to the AHA. We recognize, as stated in my June 23, 2000 letter to Dick Davidson, that providers will face challenges in implementing the new payment system. My letter also stated that erroneous claims due to inadvertent billing errors, honest mistakes or negligence would not be actionable under the False Claims Act. Nonetheless, to avoid any misunderstanding, I must note that the OIG and other agencies charged with safeguarding the integrity of the Federal health care programs and their beneficiaries may find it necessary to examine erroneous OPPS claims and a hospital's conduct to determine if such claims were submitted with actual knowledge of the falsity of the claim, reckless disregard of the truth or falsity of the claim, or deliberate ignorance of the truth or falsity of the claim.

Finally, the last paragraph of your August 11, 2000 letter indicated that the AHA was disappointed with the OIG's "objection to an increase in HCFA's contingency plan that would pay hospitals more than 70 percent of current Medicare payments originally proposed." We believe the AHA is misinformed with respect to the OIG's position on HCFA's plan to increase contingency payments from 70 percent to 85 percent of current Medicare payments. In fact, the OIG has no objection to such an increase.

I hope this responds to your inquiries.

Sincerely,

/s/

June Gibbs Brown
Inspector General

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August 11, 2000

June Gibbs Brown
Inspector General
Department of Health and Human Services
Office of Inspector General
330 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Brown:

Thank you for your letter of June 23, 2000 to Dick Davidson. The American Hospital Association (AHA) appreciates your acknowledgement that providers will face challenges in implementing the outpatient prospective payment system (OPPS). We agree with you that the False Claims Act (FCA) "simply does not cover mistakes, effors, or negligence." If these types of errors result in overpayments under OPPS they should be refunded to the program contractors.

We want to clarify this position with our membership by ensuring that they understand the appropriate process for returning any funds received through "erroneous claims" (i.e., mistakes, errors or negligence). We will also emphasize, as you did in your letter, that any funds erroneously claimed must be promptly returned to the government. But we would like to assure our members that they could return those overpayments without fear of penalty. We would like for you to review the process we have outlined below for our membership and let us know if this is contrary to what you intended.

- Our members should report any overpayments related to erroneous claims to the appropriate program contractors (e.g., a carrier or fiscal intermediary) following existing overpayment guidelines published in the respective contractor's manual. One guidance document we would refer our members to is HHS/HCFA - Transmittal No. AB-99-33 Date June 1999, Tracking and Reporting Procedures for Unsolicited/Voluntary Refund Checks from Providers /Suppliers- Interim Instructions. We understand that some contractors have issued updates and/or more specific procedures for the processing of overpayments, but in general these are instructive guidelines. Our members would follow each contractor's most current guidelines.

- It is our understanding that providers should not go through the Office of Inspector General's Provider Self-Disclosure Protocol (PSDP) for erroneous claims related to OPPS because, as stated in the protocol, the PSDP "is intended to facilitate the resolution of only matters that, in the provider's reasonable assessment, are potentially violative of the Federal criminal, civil or administrative laws." Additionally, as these are refunds of overpayments and not a self-disclosure, it is our expectation that a Corporate Integrity Agreement would not apply in this process.

Unless we receive notification from you to the contrary, we will assume that the course of action we plan to recommend to our members should overpayments result from OPPS implementation is acceptable to you.

Recent Developments. Since we received your June 23 letter, our concern about the potential for errors under OPPS has intensified, because the evidence continues to mount that the system is being prematurely implemented. Errors are to be expected during as complex and comprehensive a system change as is taking place. However, the number of errors is bound to increase due to the lack of sufficient time to adequately test, correct, and validate corrections to the system. As you know, the AHA and other associations had requested, unsuccessfully, a delay in the August I effective date. Given HCFA's insistence on maintaining the August I date, hospitals are now required to submit claims under a new system that we don't believe is ready for them.

As a result, providers are risking the consequences of holding claims and receiving no payment, or submitting claims using their best judgment while relying on instructions that in some instances HCFA admits are incomplete or incorrect. The lack of complete, accurate, and timely instructions for billing, combined with the known software programming issues and delays, will lead to mistakes in claims and payments, and the rejection, denial and subsequent resubmission of claims.

To illustrate the situation hospitals face, we are listing below some of the unsettled issues. For some of these issues, HCFA has reported that missing or corrected information will only be available in October or later. Of course, this list cannot begin to describe the full range of issues that will be experienced as claims are submitted. We have communicated extensively with HCFA about problems with the new system through a series of letters beginning in February of this year, as well as a variety of meetings and calls. Over the recent months we have been in contact on at least a weekly basis. The issues that concern us include, but are not limited to, the following:

- A fundamental problem is that the coding system was designed and developed to describe the services and procedures provided by a physician on an outpatient basis. The codes were not intended to describe, nor do they accurately reflect, the services provided by a facility in connection with an outpatient encounter. While HCFA has assigned codes for some items, to a large extent HCFA has directed hospitals to develop their own "cross-walk" for assigning codes to facility services. This makes it very difficult to accurately determine which codes to use.

- HCFA is providing guidance to hospitals through a variety of means, e.g., the regulation, the manual, the frequently asked questions (FAQ), and oral statements of HCFA staff at the town hall and other forums. On several matters the government's position varies from one guidance to the next, and the answers in the FAQ are still changing. This makes it very difficult for hospitals to know which position to act on.

- The code editor (OCE), which groups data into ambulatory payment classifications (APC) and edits the data, does not always match the provisions of the final rule. Again, discrepancies in the government's guidance make it very difficult for hospitals to know what is required.

- It is still not clear whether beneficiaries are responsible for a deductible with blood products.

- There is lack of direction on coding for some services that involve more than one procedure, one of which is to be billed on an inpatient-only basis and the other as an outpatient.

- There is inconsistency in billing instructions for two separate and independent encounters on the same day if one of the encounters is part of a series of planned treatments.

- There is inconsistency on how to submit claims for "noncovered" items so that, as is currently the case, there is required documentation for a beneficiary's secondary insurer to accept a claim.

We cannot over-emphasize the difficulty that the lack of timely and accurate guidance is causing providers. The ability to adequately prepare their systems and staff for this most complex and demanding change has been seriously impeded. In addition to the lack of sufficient information to guide the coding and claims process, the lack of interface with the PRICER software makes it impossible for a provider to monitor the accuracy of the payments being made by the fiscal intermediary and the appropriateness of coinsurance billings to the beneficiary.

While we agree with you in general that an effective voluntary compliance program could be helpful to hospitals in this situation, their ability to have an effective program for OPPS has been severely compromised by the absence of clear, accurate and timely information from HCFA. We will continue to closely monitor implementation of the new system and keep you apprised as we convey our concerns and the problems to HCFA.

In closing, we must also advise you of our disappointment in your objection to an increase in HCFA's contingency plan that would pay hospitals more than the 70 percent of current Medicare payments originally proposed. Given the inability of hospitals to collect the coinsurance or receive payments from Medigap plans if HCFA's systems are not working, a contingency payment that represents only 3 5 percent of total expected OPPS payments was completely unacceptable. While the contingency payment has been increased to 42.5 percent, we see no reason for hospitals to bear the risks associated with significantly restricted cash flow after the government's decision to move forward with OPPS in the absence of reasonable assurances that the system would perform as intended. We ask that you reconsider your objection and agree to an increase in the contingency payments as recommended by HCFA.

Sincerely,

/s/

Rick Pollack
Executive Vice President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General
Washington, D.C. 20201

June 23, 2000

Mr. Dick Davidson
American Hospital Association
325 Seventh Street, NW
Washington, DC 20004

Dear Mr. Davidson:

Representatives of the American Hospital Association ("AHA") have related to the Office of Inspector General ("OIG") that many AHA members have concerns with the upcoming implementation of the hospital outpatient prospective payment system ("HOPPS"). According to AHA, some of its members believe that HOPPS is such a new and complex system that coding and billing errors are likely to occur as hospitals and fiscal intermediaries work through the implementation process. As such, the AHA has requested from the OIG a statement of enforcement policy in light of the issues surrounding HOPPS implementation.

First, as we have stated in the past, under the law, hospitals are not subject to civil or criminal penalties for innocent errors, mistakes or even negligence. The Government's primary enforcement tool, the civil False Claims Act ("FCA"), covers only offenses that are committed with *actual knowledge* of the falsity of the claim, *reckless disregard* of the truth or falsity of the claim, or *deliberate ignorance* of the truth or falsity of the claim. The FCA simply does not cover mistakes, errors, or negligence. The other major civil remedy available to the Federal Government, the Civil Monetary Penalties Law, has exactly the same standard of proof. The OIG is very mindful of the difference between innocent errors and negligence ("erroneous claims") on the one hand, and reckless or intentional conduct ("fraudulent claims") on the other.

When billing errors, honest mistakes or negligence result in erroneous claims, the hospital will be asked to return the funds erroneously claimed, but without penalties. In other words, erroneous claims result only in the return of funds claimed in error. Nevertheless, inadvertent billing errors are a significant drain on the programs and all parties need to work cooperatively to reduce the overall error rate.

We recognize that providers will face challenges in implementing the new payment system, and it is during such challenging times that providers need to be especially vigilant in identifying erroneous claims. We believe an effective voluntary compliance

program can help hospitals identify erroneous claims, correct the underlying problems causing the erroneous claims and ensure that any overpayments caused by such erroneous claims are promptly returned to the Government. But again, it should be emphasized that civil or criminal penalty action will not be initiated for billing errors due to inadvertence or negligence,

Should a question of improper billing under HOPPS by a hospital arise, as in all cases, in assessing whether there is sufficient knowledge to trigger civil or criminal penalties, the OIG will look at a variety of factors, including (1) the clarity of the relevant rule; (2) the complexity and novelty of the billing system at issue; (3) the guidance issued by HCFA and/or its agents (e.g., fiscal intermediaries); (4) the extent to which the provider has attempted to ascertain an understanding of the relevant rule; (5) the quality of the efforts of the provider to train personnel on the billing system; and (6) whether the provider has an effective compliance program in place. This list is merely illustrative in order to give your members an appreciation for the kinds of factors the OIG evaluates when investigating allegations of fraud and should not be construed as an exclusive list of factors.

We hope that the foregoing has made it clear that the OIG's law enforcement efforts are not directed toward erroneous claims. Rather, they are focused on false or fraudulent claims that are submitted with the requisite level of intent or knowledge to trigger civil or criminal penalties.

Should you have questions or need of further assistance regarding this issue, please feel free to contact D. McCarty Thornton, Chief Counsel to the Inspector General, at (202) 619-0335).

Sincerely,

/s/

June Gibbs Brown
Inspector General