April 16, 2012

VIA COURIER AND ELECTRONIC MAIL

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-9989-P
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: Comments on Proposed Rule: Medicare Program: Reporting and Returning Overpayments (CMS-6037-P) 77 *Fed. Reg.* 9,179 (Feb. 16, 2012)

Dear Ms. Tavenner:

The Federation of American Hospitals ("FAH") is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay and long-term care hospitals in urban and rural America, which provide a wide range of ambulatory, acute and post-acute services. We appreciate the opportunity to comment to the Centers for Medicare & Medicaid Services ("CMS") about the referenced Notice of Proposed Rulemaking on Reporting and Returning Overpayments ("Proposed Rule").

GENERAL COMMENTS

I. Hospitals and CMS Share the Goal of Ensuring Proper Medicare Payments

Hospitals and CMS share the important goal of ensuring proper Medicare payments. Hospitals devote substantial resources at significant cost to maintaining processes which facilitate proper Medicare billings and cost reports in the first instance, not to mention monitoring program remittance to identify and correct identified improper payments. Through their voluntary compliance programs, hospitals have long strived to meet the goal of proper payments from government health care programs, including building front-end infrastructure to help "get it right the first time" to the best of their abilities.

We appreciate that CMS also devotes significant resources to help hospitals fulfill their obligations to file proper Medicare claims and costs reports. However, in a program the size, magnitude, and complexity of Medicare, the reality is that there are ambiguities and uncertainties about applicable rules and guidance, including how Medicare contractors interpret CMS policies. There also is the risk for human error given the intricate rules and large volume of Medicare billings hospitals submit. Unfortunately, these realities can result in improper Medicare payments, which affect the Medicare error rate, a metric that is an important management tool for CMS.

The FAH believes the Proposed Rule should have adopted the tone of a Medicare payment rule, and be consistent with existing Medicare payment policies. FAH members were surprised by the Proposed Rule's overall direction, inconsistencies with existing Medicare payment policies, and the inferences that result from the proposed policies. More directly, the Proposed Rule reads like a fraud and abuse enforcement policy, and creates an aura that every Medicare overpayment is the byproduct of suspicious behavior of providers and suppliers.

For example, the proposed definition of "identified" and the proposed ten-year look-back period mirror existing fraud and abuse authorities, and are inconsistent with existing Medicare payment policies. (These issues will be discussed in more detail below in the Specific Comments section.) We question whether this is a constructive approach to implementing this new authority, as FAH hospitals cannot accept the premise that every improper Medicare hospital payment results from bad acts.

FAH member hospitals consider themselves to be partners with CMS in ensuring that Medicare beneficiaries get the appropriate, high quality medical care they need, when they need it. Hospitals endeavor in good faith to submit proper Medicare claims and cost reports when seeking reimbursement for that care, and are accustomed to self-correcting identified errors or to responding appropriately to third parties when contacted about potential payment discrepancies. **We respectfully urge that the tone, direction and substance of a final rule reflect the important partnership that hospitals and CMS share, and the reality that hospitals, on a daily basis, operate in good faith to seek proper Medicare payments**.

II. The Overpayment Refund Policy Should Use Existing Procedures Whenever Possible

The Proposed Rule proposes to implement the reporting and refund obligation using the existing voluntary refund process found in Chapter 4 of the Medicare Financial Management Manual ("MFMM"), which incorporates by reference the Medicare Program Integrity Manual. It is true that providers and suppliers sometimes use this process. However, this process currently is not required as the only way for voluntary overpayment refunds to be made, and is usually only used when a refurn is being made by check. In fact in most overpayment cases, other processes are used that are effective and efficient, both for the Medicare program and providers and suppliers.

Notably, overpayments can take different forms. Generally, Chapter 3 of the MFMM describes two types of overpayments – aggregate and individual. Aggregate overpayments are described as those involving a group or all of a Part A provider's claims, such as those discovered during cost report settlement or those resulting from a pattern of improper application of Medicare coverage provisions. Individual overpayments are defined as incorrect claims payment for services under Part A or Part B, such as those for non-covered items and services or incorrect application of coinsurance or deductible. Individual overpayments tend to occur during the normal claims processing cycle. Today, providers and Medicare contractors work together to resolve individual overpayments using existing claims processing procedures. Requiring the use of the overpayment

refund and reporting process for these types of overpayments would be unduly burdensome for both providers and contractors.

Because overpayments take different forms, we believe CMS should not limit the manner in which an overpayment refund may occur to the existing voluntary refund process. A one-size-fits-all approach is likely to be unwieldy, and in many cases will place a significant burden on hospitals. It seems plausible that the proposed approach in practice could result in situations where workloads double because hospitals use existing procedures and file the proposed overpayment report. This is not an appropriate outcome in an environment where hospitals are pressured constantly to hold down administrative costs, and are facing a long period of declining Medicare reimbursement.

Instead, CMS should permit providers and suppliers to refund overpayments using the adjustment bill process, credit balance reports, or other existing procedures for returning overpayments. These existing processes are well-known to hospitals and Medicare contractors, and work effectively and efficiently for all parties at recouping overpayments. In our members' experience, Medicare contractors prefer that hospitals submit adjusted bills so that each beneficiary's account properly reflects how and why the payment was adjusted or how the contractors recouped a full or partial overpayment. Given the adjustment bill includes the reason for the adjustment, it informs contractors so that re-reviews of the same account are not undertaken for the same reason.

In fact, our members have been directed not to issue refund checks of overpayments on accounts that can be corrected through adjustment bills, as doing so often leads to overpayments being recovered twice by the Medicare program. Providers are currently required to submit an adjustment reason code, which would allow the contractor to aggregate and report on overpayments returned to the program. If CMS desires more specific information collection, we urge it to modify the adjustment bill's data fields, and not to undertake a wholesale pivot to the voluntary refund reporting form.

Complying with the Proposed Rule's written voluntary refund report requirement in every instance, given the detailed data elements, would place a significant burden on hospitals and produce voluminous refund reports, which busy Medicare contractors are unlikely to scrutinize consistently due to their existing operational responsibilities. Our recommended approach would reduce the Proposed Rule's significant burden on all parties. We welcome the opportunity to work with CMS to identify an approach that balances reasonably the needs of stakeholders.

Also, we question whether the magnitude of data elements proposed to accompany the voluntary refund will be necessary in each and every case. For example, the Proposed Rule includes the following two data elements to be included in every report: (1) how the error was discovered; and, (2) a description of the corrective action plan implemented to ensure the error does not occur again. Notably, these two elements are not a part of the minimum data reporting requirements currently included in the CMS Manuals, and seem to go beyond the statutory reporting and refund obligation. Thus, we request that CMS remove these two items from any such requirements.

III. CMS Should Interpret this Authority to Permit Payment of Provider Underpayments

In the spirit of partnership that hospitals and CMS share, CMS should permit hospitals to receive payments related to Identified Medicare underpayments. Medicare payment errors often go both ways, with many cases involving underpayments to hospitals. In the interest of promoting the goal of proper Medicare payments and reaching a fundamentally fair policy, CMS

should allow providers and suppliers to recoup underpayments for the same time period to which the final rule applies.

For example, the Proposed Rule would impose a ten-year look-back period when a provider or supplier reports an overpayment, but would not increase the reopening period under 42 C.F.R. §405.980(b) to allow contractors to reward additional payments. Yet, the same provider or supplier initiated audit or investigation may reveal underpayments as well as overpayments, but without the ability to correct both in a consistent manner. In the interest of the partnership providers and suppliers share with the Medicare program, we urge CMS to promulgate consistent policy to ensure proper Medicare payments.

There is precedent for our recommendation. The Recovery Audit Contractor ("RAC") program requires RACs to refund any identified underpayments in addition to recouping identified overpayments. This policy exemplifies CMS's recognition of the fundamental fairness provided by a two-way approach, and should be adopted here.

IV. The Final Rule Should Include a Materiality Threshold

The Proposed Rule would impose a substantial burden on providers and suppliers under the reporting and refund obligation provisions, especially if the existing adjustment bill process is not available as a means to refund overpayments. **We urge CMS to implement a materiality standard to apply to the new overpayment report and refund policy.** We think it is appropriate for CMS to consider a cost-benefit analysis requiring the proposed process to be followed for every overpayment, no matter how small. For example, in its approach to Corporate Integrity Agreements ("CIAs"), the Office of Inspector General ("OIG") recognizes a materiality threshold in that CIAs often permit the offset of underpayments to overpayments. The OIG does this for purposes of calculation a net financial error rate, which then is used to determinate whether a sample review must be expanded to a larger review.

In our view, there could be many situations where the cost and resources associated with reporting and refunding the overpayment greatly exceed the amount of the overpayment. In effect, CMS should not create a policy which results in expending unlimited resources and expense to chase pennies.

This recommendation has many implications, so we understand that this idea may be challenging to effectuate in practice. The FAH welcomes the opportunity to work with CMS on this issue to strive to find an appropriate balance to the policy. With declining reimbursements and hospitals experiencing financial losses serving Medicare patients, it would seem to be reasonable public policy to allow hospitals and Medicare not to spend resources on developing reports on refunds, when the cost of doing so exceeds the value of the claim to be refunded.

In support of our recommendation, we note that a materiality standard is included in other areas of Medicare payment policy and related fraud and abuse enforcement policies. For example, the Medicare Financial Management Manual instructs Medicare contractors not to attempt recovery of overpayments under $10. (*See* MFMM Ch. 3 §170.2.) Similarly, under the physician self-referral law, certain incidental medical staff benefits with limited value (less than $31 for 2012) are deemed insufficient to give rise to a financial arrangement to which the statutory referral prohibition applies. (*See* 42 C.F.R. §411.357(m).) Moreover, CMS currently follows a materiality threshold of $300 for Medicare Secondary Payer liability recoveries. Finally, under the Civil Monetary Penalty Law, the Office of Inspector General enforces only the prohibition against improper remuneration to patients

when the remuneration exceeds $10 for each item or $50 in the aggregate. (*See* HHS OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries: 67 *Fed. Reg.* 55,856 [Aug. 30, 2002].)

V. The Regulatory Impact Statement Grossly Underestimates the Burden on Providers

The Proposed Rule's regulatory impact statement grossly underestimates the burden on hospitals, especially if every overpayment needs to be refunded using the MFMM's voluntary refund process. **We strongly urge CMS to reconsider its Regulatory Impact Analysis to take into account all factors around resource utilization, and then reconsider the policy in light of the accurate level of burden the Proposed Rule imposes on hospitals.**

First, the impact statement estimates that the annual number of overpayments from a provider or supplier will range from three to five instances per year. This estimate does not seem plausible under any scenario, especially given the volume of Medicare payments and the ambiguities in Medicare payment policy. Overpayments often can occur as a result of routine errors by the Medicare contractors in processing claims or as a result of data errors that are not identified through front end claims edits processes, by both the hospital and the Medicare program, during the initial processing and payment of claims. For example, changes to payer systems required by the HIPAA 5010 transaction standards resulted in a high volume of errors on the payer side, all of which would appear to constitute overpayments under the Proposed Rule.

In our members' experience, errors of this type represent only a slight percentage of the total universe of claims submitted to Medicare. However, even a small percentage of total Medicare claims will equate to a number of overpayments far greater than three to five instances per year. One of our members estimates that it routinely processes hundreds of adjustment bills in a typical day. Therefore, the Proposed Rule dramatically understates the number of overpayments to which the new policy would apply.

Second, the impact statement indicates that providers and suppliers will spend two and a half hours meeting their overpayment report and refund obligations. This estimate also grossly underestimates the average amount of time currently spent on this type of activity and does not account for the additional investment in infrastructure likely to be necessary to manage risk under the Proposed Rule's definition of "identification" (discussed below).

From an oversight perspective, hospitals may have multiple operating divisions involved in an overpayment situation, depending on their particular approaches. The people who are involved in assessing an overpayment situation begin with the billing staff that participated in the original claim submission and, depending on the situation, may be expanded to include internal audit and/or compliance staff, and in-house or outside legal counsel.

As the RAC experience shows, the amount of time spent on a particular overpayment is also dependent on whether the overpayment was identified through automated processes or as a result of complex medical review to assess medical necessity. Cases involving medical necessity determinations often involve payment policy ambiguity, requiring the use of additional personnel, such as clinical, quality assurance and/or case management personnel. With the volume of complex medical reviews increasing, this type of overpayment review activity is becoming increasingly more prevalent, and should produce a longer time estimate in this context.

The need to coordinate members of a group involved in an overpayment situation, regardless of its composition, requires even greater resource utilization. While there may be a rare case to the contrary, researching overpayments and preparing refunds is considerably more complex and resource intensive than the Regulatory Impact Statement estimates, especially when considering the proposed process and data elements.

Finally, multiple year reviews affect the amount of time spent by hospitals. The farther back a particular review goes, the harder it is to identify and locate all pertinent information. Given the proposed ten-year look-back period, we think the Proposed Rule's estimate on his point is deficient.

SPECIFIC COMMENTS

I. The Proposed Definition of "Identified" for Purposes of Determining an Overpayment Goes Beyond the Statutory Boundaries and Imposes an Unreasonable Burden on Hospitals

The Proposed Rule states that "[a] person has identified an overpayment if the person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment," the latter part which also is known as a "should have known" standard. (42 C.F.R. Proposed §401.305(a)(2).) The preamble states that this interpretation of "identified" is necessary to give "providers and suppliers an incentive to exercise reasonable diligence to determine whether an overpayment exists. Without such a definition some providers and suppliers might avoid performing activities to determine whether an overpayment exists, such as self-audits, compliance checks, and other additional research."
(77 *Fed. Reg.* at 9,182.)

At its core, we question the statutory authority for the proposed definition of "identified." Moreover, the Proposed Rule would create a very significant burden on hospitals that goes beyond existing processes already being used effectively to mitigate the risk of improper Medicare payments. Finally, the FAH disagrees that the proposed approach is necessary to meet CMS's stated objective, which we believe could be achieved in a much more efficient and direct manner.

In summary, CMS should scale back the proposal to meet the statutory directive, which is to require reporting and returning an overpayment when a hospital has actual knowledge than an overpayment exists. This interpretation would be consistent with the plain reading of the Affordable Care Act ("ACA") §6402(d)'s use of the term "identified," as well as how that section amends the OIG's Civil Monetary Penalty ("CMP") authority, which only permits CMPs to be imposed when a person has actual knowledge of an overpayment and does not report and refund the overpayment as required. Notably, the similar CMP authority does not impose a "should have known" standard as a basis for CMP liability.

A. The Statute Does Not Support The Proposed Definition of "Identified"

The appropriate starting point is the statutory text. ACA §6402(d) imposes an obligation to report and return Medicare overpayments. Specifically, the statute reads "[i]f a person has received an overpayment, the person shall" report and return the overpayment "by the later of - (A) the date which is 60 days after the date on which the overpayment was identified" or the date any corresponding cost report is due.

The statute contains a definition of the terms "knowing" and "knowingly," but importantly those terms are not included anywhere in the section's substantive policy provisions. The Proposed Rule acknowledges that the terms "knowing" and "knowingly" are not used anywhere in the substantive policy, yet, CMS nonetheless attempts to shoehorn this standard into the policy, with very significant ramifications and burdens for hospitals. **In our view, the statute's definition of "knowing" and "knowingly" amounts to nothing more than extraneous text, and should be ignored for purposes of implementing the overpayment report and refund obligation.**

Logically, the statute can be read to impose inferentially a reasonable standard of actual knowledge of an overpayment to trigger the duty to report and refund. This is the best reading of the operative phrase "[i]f a person has received an overpayment . . . ." But, CMS seeks to define the word "identified" in a way that broadens the universe of potential overpayments to include those that a hospital "should have known" about. We believe the approach amounts to an overreaching attempt to infuse the hanging definition of "knowing and knowingly" into substantive policy. If Congress had intended the meaning ascribed by the Proposed Rule, then the term "knowingly" would likely have been used in a way that modified the term "received," and not as CMS attempts to do with the term "identified."

In contrast, the statutory term "identified" is used only in the context of defining an appropriate trigger for the 60-day report and refund clock to begin. This focal point is important to keep in mind, because the Proposed Rule confuses the concepts in a way that leads to an illogical outcome and the practical impossibility that a 60-day clock begins to run on a date that a hospital "should have known" about an overpayment, although it actually had no knowledge at all.

We are unable to reach any other conclusion other than that the Proposed Rule essentially creates a "gotcha" situation, because there is no practical way for providers and suppliers to comply. It also raises a whole host of other sticky factual issues, including what would be the appropriate date on which the hospital should have known, and who is the appropriate party to make this finding. The better reading of the statute avoids all of these other implications and factual issues likely to lead to disputes and delays.

B. The Proposed Definition of "Identified" Imposes an Unreasonable Burden on Hospitals Through a Full Scale Duty to Audit

The practical implications of the proposed definition of identification are enormous, far ranging and would impose an unreasonable administrative burden on hospitals. The Proposed Rule could be read as imposing, as a practical matter, a broad duty to conduct full-scale audits that go well beyond the statutory requirement to report and return overpayments. This proposal will impose new infrastructure and expense obligations on hospitals that will increase the cost of health care services furnished to Medicare beneficiaries. Corporate Compliance Officers from several FAH members have expressed concern that the breadth of the Proposed Rule effectively would require their hospitals to hire additional resources to provide an independent review of, or a "second set of eyes" on, their Medicare billings and cost reports when the hospitals have no knowledge of any actual errors. This new infrastructure would be needed to address operations that would go beyond what the statute contemplates (*i.e.*, an obligation to report and refund known overpayments) and would essentially create a broad spectrum audit process without regard to whether an overpayment exists or not.

CMS's rationale for its interpretation is that it will provide a necessary incentive for providers and suppliers to investigate for overpayments and not to avoid self-audit activities. However, there is a material difference between a duty to investigate when information about a potential overpayment is

at hand, versus a duty to audit essentially every claim to make sure that the original billing or cost report staff "got it right" in the first instance. Indeed, CMS's approach, endorsing what appears to be a duty to a full scale audit, essentially amounts to a presumption that something could have been wrong with a claim in the first instance, and as such, a hospital should have known it has been overpaid.

Our concern is not just about the risk of Medicare contractor enforcement in "should have known" situations, but also more pointedly about creating a potential fertile field for whistleblowers under the Federal Civil False Claims Act ("FCA"). By employing a "should have known" standard for overpayment refunds, the risks to, and attendant burdens on, hospital compliance programs would go up exponentially to manage these significant compliance risks, which would be magnified considering the volume of Medicare claims hospitals file daily.

C. CMS Should Narrowly Tailor a Duty To Investigate

We recognize CMS's legitimate concern that this policy not allow for hospitals to avoid the overpayment report and refund obligation when there is some indication of a potential overpayment, simply by avoiding doing additional investigatory work to bring an issue to conclusion. Hospital voluntary compliance programs already follow this basic duty to investigate, so a parallel, narrowly drawn duty to investigate would seem appropriate here.

An appropriate standard would be to require a duty to investigate when there is "credible evidence of the existence of an overpayment." This standard could apply to a variety of fact patterns, including, but not limited to, compliance hotline communications, internal statistical analyses identifying potential payment discrepancies, and issues raised by hospital staff. We believe this approach would satisfy CMS's stated concern, while imposing a more reasonable administrative burden on hospitals.

As noted above, the statute uses the term "identified" to define the trigger for the 60-day reporting and refund obligation. **With regard to a duty to investigate, the 60-day timeline should <u>not</u> be triggered when a hospital learns of credible evidence of the existence of an overpayment, but instead should accrue when the investigation reaches the point where an actual overpayment is clearly identified.** To start the 60-day period when a hospital only has credible evidence of the existence of an overpayment would impose an unreasonable burden on hospitals to expedite their review under an already aggressive timeline. Such an approach would technically tie the duty to report to a finding of credible evidence and not to an actual overpayment determination, an approach which is not supported by the statute.

II. The Proposed Rule's 60-Day Requirement for Reporting and Refunding Overpayments Is Too Rigid and Needs Greater Flexibility

ACA §6402(d)(4)(b) defines "overpayment" as any Medicare or Medicaid funds a person receives or retains to which "the person, <u>after applicable reconciliation</u>, is not entitled . . . ."[1] (Emphasis added.) However, the Proposed Rule gives effect to the phrase "after applicable reconciliation" only in the context of interim payments that later are reconciled on a hospital's cost report. We believe the operative language should be read less narrowly to apply also to claims-based payments, which would be more consistent with Congressional intent.

[1] We note that the Proposed Rule does not address this authority regarding Medicaid overpayments at this time.

There is a clear dichotomy between when a potential overpayment is identified and when an actual overpayment is identified. Depending on the type of potential overpayment, the investigatory work necessary to reach the status of an actual overpayment may take a short or long time to accomplish, even in the best of circumstances. Congress included the "after appropriate reconciliation" language in recognition of the fact that an overpayment investigation is a deliberative process which takes time to administer and complete. For this reason, there is not, by definition, an "overpayment" until that point in time when an actual overpayment is identified. This interpretation gives appropriate meaning to all the statutory words and better recognizes Congressional intent, and better explains Congress's justification for the report and refund obligation's 60-day time period.

A separate but related issue is whether CMS should impose a standard for the timeframe within which a hospital must conduct and complete its investigation of whether an actual overpayment exists. On this point, the Proposed Rule indicates that an investigation should proceed "with all deliberate speed." **The FAH is concerned that this standard is too rigid, does not take into account operational realities, and implies a uniform approach when overpayments situations come in different shapes and sizes requiring different levels of resource utilization. Instead, the FAH urges an approach that would allow for a "reasonable period of time to investigate" a potential overpayment.** This approach is similar to the existing approach used by Medicare Contractors, and in practice should lead to a more objective assessment of an appropriate timeframe for completing a review of a potential overpayment situation.

Our recommended approach also dovetails nicely with our view on the proper duty to investigate, such that the overpayment report and refund obligation should be triggered when an actual overpayment is identified, and not just when credible evidence of the existence of an overpayment is present.

Under our proposed construct, the proposed data elements requesting a description of the corrective action plan developed to avoid future errors and whether a provider or supplier is under a CIA with the OIG are not germane to a true overpayment situation and should be eliminated from the final policy.

III. A Ten-Year Look-back Period Is Inconsistent with Existing Reopening Policies, and Runs Counter to the Well-Established Principle of Administrative Finality for Medicare Payments

The Proposed Rule requires that overpayments be reported and refunded when a person identifies an overpayment within ten years of the date of the overpayment. (*See* 42 C.F.R. Proposed §401.305(g).) The Proposed Rule also seeks to amend an existing reopening regulation at 42 C.F.R. §405.980 to make a conforming change to recognize a ten-year reopening period in this context. (*See* 42 C.F.R. Proposed §405.980(b)(6).) The FAH opposes both proposals to implement an expansive look-back period, because they are inconsistent with existing Medicare reopening authority and long-accepted principles of administrative finality for Medicare payments.

Currently, the Medicare claims reopening regulation states as follows:

> A contractor may reopen and revise its initial determination or redetermination on its own motion—
>
> > (1) Within 1 year from the date of the initial determination or redetermination for any reason.

> (2) Within 4 years from the date of the initial determination or redetermination for good cause as defined in §405.986.
>
> (3) At any time if there exists reliable evidence as defined in §405.902 that the initial determination was procured by fraud or similar fault as defined in §405.902.

(42 C.F.R. §405.980.) Further, a hospital's "reasonable expectation of administrative finality" is recognized in multiple Medicare manuals. (*See e.g.*, Centers for Medicare & Medicaid Services, *Medicare Claims Processing Manual*, Ch. 34 §§ 10.6.2, 10.7; Centers for Medicare & Medicaid Services, *Provider Reimbursement Manual*, Ch. 29 § 2930.) For many years, hospitals have enjoyed (and courts have upheld) a reasonable expectation of administrative finality for Medicare payments.

ACA §6402(d) makes no changes to existing statutory authorities related to reopening or settlement of claims, which are found at Social Security Act ("SSA") §1869 (the legal basis for the claims reopening regulations) or SSA §1870 (which addresses overpayments and settlements of claims). Both of these statutory sections recognize the need to recover overpayments, but do so in a way that reasonably balances how far back one must go to meet this obligation against the burden of retroactive action. Notably, SSA §1870, which the ACA does not amend, authorizes the Secretary to shorten the recoupment period, but not extend it.

Despite this clear and well-settled background, the Proposed Rule essentially would create a separate repayment standard for self-identified overpayments that would not apply to overpayments identified by the Medicare program. This inconsistency is illogical, and places a significantly greater burden on hospitals than the Medicare program places on itself. Under SSA §1870, in the absence of fraud or similar fault, funds received improperly by hospitals which are identified after four years from the date of an initial or revised determination are <u>not</u> "overpayments" for purposes of Medicare contractor recoupment. Thus, for consistency purposes, they should not constitute "overpayments" for purposes of the voluntary refunds emanating from provider self-identification situations, because ACA §6402(d) only applies to payments to which the provider or supplier is "not entitled."

The proposed ten-year look-back period is more consistent with the outer limit of the statute of limitations of the Federal FCA, a key fraud and abuse statute enforced by the Department of Justice. In fact, this is the exact and sole reason that CMS cites in support of the proposed look-back period. (*See* 77 *Fed. Reg.* at 9,184.) The FCA is a separate civil liability statute with an entirely different focus designed to correct fraud cases and, even under this statute, a ten-year look-back period is not the usual statute of limitations, just an outer limit.

This proposal gives rise to our main concern about the Proposed Rule reading more like a fraud enforcement rule than a Medicare proper payment rule. We see no logical basis to use the FCA's statute of limitation as an appropriate proxy in this context, and contend that such an approach would be arbitrary, capricious and an abuse of discretion, especially if CMS were to maintain the "should have known" standard related to identifying overpayments. Using this approach in a Medicare payment rule implicates a whole host of other factual issues that Medicare contractors are not well equipped to handle (*e.g.*, the "imputed knowledge" issue, which focuses on when should an employee's knowledge of an overpayment be imputed to the provider or supplier for purposes of the 60-day time period.)

Also, as a practical matter, the ten-year look-back period runs counter to many hospitals' document retention policies, which are set at timeframes significantly lower than ten years. The burden and resources associated with hospitals' expansion of existing record retention policies will be significant, and add to the cost of providing health care to Medicare beneficiaries with little practical benefit to the program.

Here, the FAH believes the look-back period for purposes of the reporting and refunding of self-identified overpayments should be four years, which is consistent with the current reopening rules at 42 C.F.R. § 405.980. This ensures consistent application of the duties of hospitals and the Medicare program with regard to overpayment refunds and recoupments, and honors accepted principles that provide a presumption for administrative finality of Medicare claims payments.

There is an additional category of potential overpayments that seems deserving of special mention. Consider the following hypothetical. A Medicare contractor conducts a post-payment audit for a time period which is less than the refund time period imposed by CMS under this new policy, and determines that a hospital has been overpaid for certain types of Medicare claims. The contractor's determination which gives rise to the overpayment recoupment should not create an affirmative duty for hospitals to review similar cases for the additional time period up to the outer limit of CMS policy. This approach is reasonable, reduces provider costs related to program services, and is in line with accepted principles of administrative finality. However, without a clear statement to the contrary, the Proposed Rule appears to stand for the proposition that providers and suppliers would be required to review similar claims for other time periods not addressed by a contractor's post-payment audit.

IV. The Proposed Rule's Expansive Look-Back Period Raises Serious Concerns about Impermissible Retroactive Rulemaking

The Proposed Rule's expansive ten-year look-back period and conforming amendment to the Medicare claims reopening regulation also raise serious concerns as to whether the 60-day report and refund rule will be applied retroactively. On its face, the ACA does not provide for retroactive application of this new policy, and Congress generally has not granted CMS retroactive rulemaking authority. Thus, it seems clear that, as a legal matter, the new policy's deadlines do not apply to overpayments before March 23, 2010, which is the date of the ACA's enactment. To conclude otherwise would result in a contrary interpretation that conflicts with existing case law[2] and with Medicare's "without fault" rules[3].

The potential for retroactive application also creates a practical anomaly. Under current law, Medicare claims paid in years 2002 through 2007 are closed and final, because they are outside the applicable reopening period and are entitled to protection under the notion of administrative finality over Medicare payments. The Proposed Rule, however, would upend this important concept of

[2] This possible interpretation would conflict with the District Court's decision in *U.S. ex rel. Stone v. Omnicare, Inc.* (N.D. Ill. July 7, 2011), 2011 WL 2669659 at *2-*4, which found that such a theory would create "impermissible retroactive effect" and that because the ACA is silent regarding retroactivity, identification of an overpayment must occur after the passage of the ACA for the duty to report and refund to apply.

[3] *See, e.g.*, 42 U.S.C. §1395gg(c) and 42 C.F.R. §405.350(c), which stands for the proposition that, absent contrary evidence, persons who receive Medicare payments are considered without fault if the applicable payer determines the payment amount was incorrect after the third year in which the payment was made. In this situation, payments subject to this new policy may not even constitute overpayments at all, because by virtue of the without fault rules, such payments may not even constitute amounts to which the provider is "not entitled."

administrative finality and create the potential for reviving these claims for review under the FCA. Thus, the Proposed Rule essentially is engaging in prohibited retroactive rulemaking, because a federal agency cannot impose new duties or liabilities for already completed transactions when it amounts to a retroactive punishment of conduct pre-dating the announcement of the new policy. (*See Landgraf v. USI Film Prods.*, 511 U.S. 244 (1994).) It seems clear that claims paid between 2002 and 2007 would be completed transactions for purposes of this Supreme Court case precedent.

V. CMS Should Issue a Standard Voluntary Overpayment Reporting Form and Instructions

As noted above, the FAH believes that hospitals should be allowed to use existing processes to report and refund overpayments under ACA § 6402(d), and should not be required to use solely the existing voluntary refund reporting protocol in the MFMM.

However, we do support having the MFMM voluntary refund protocol continue to be one of the available processes for returning overpayments under ACA § 6402(d). In this regard, we note the Proposed Rule indicates that CMS will issue eventually a standard overpayment report and refund form with consistent guidance.

We urge CMS to issue a standardized form and instructions at the earliest opportunity. Today, contractors utilize different forms and instructions, which make the overpayment refund process confusing and burdensome, particularly for multi-hospital systems like many FAH members. A common form and instructions would promote consistency in data collection and format, reduce contractor variation, and allow hospitals to manage this process more efficiently.

VI. The Proposed Tolling Period Should Be Applied Consistently for Both CMS's Self-Referral Disclosure Protocol and the OIG's Self-Disclosure Protocol

The Proposed Rule indicates that the deadline for returning an overpayment will be suspended when the OIG and CMS acknowledge receipt of a submission to their Self-Disclosure Protocol and Self-Referral Disclosure Protocol, respectively, until such time as a settlement agreement is entered, the person withdraws from the applicable protocol, or the person is removed from the protocol. (*See* 42 C.F.R. Proposed §401.305(b)(2).) The FAH supports this policy.

However, the preamble discussion of this suspension/tolling period creates a distinction that we think should not be finalized. For purposes of the OIG protocol, a submission acknowledged by the OIG will qualify as a "report" for purposes of this policy, whereas persons making a submission acknowledged by CMS under the Self-Referral Disclosure Protocol will still need to "report" the overpayment as required to a Medicare contractor. We see no rationale to support the inconsistent approach to the duty to report, and are concerned about the duplicative work that will be required for submissions to the CMS protocol.

We urge CMS to adopt a consistent approach that recognizes that submissions accepted by the OIG and CMS under their respective disclosure protocols satisfy the duty to report for purposes of ACA § 6402(d), along with tolling the refund timeline.

VII. The Interpretation of "Reconciliation" in the Cost Report Context Is Overly Restrictive

The Proposed Rule indicates that an "applicable reconciliation" occurs when a cost report is filed, except that any changes to the SSI ratio which affect the Medicare hospital disproportionate share payments and any reconciliation to outlier payments will not result in a refund obligation until such time as the final reconciliation of the hospital's cost report occurs. (*See* 42 C.F.R. Proposed §401.305(c).) We support the proposed exceptions to applicable cost report reconciliation, but do not believe the exceptions go far enough.

The FAH believes that a better policy is that a refund obligation should not accrue for any cost report issues subject to audit by a Medicare Administrative Contractor, provided that, upon discovery by the hospital, a disclosure is made to the MAC for purposes of preparing a final cost report settlement.

VIII. The Final Rule Should Provide a Means for Providers and Suppliers that Mistakenly Refund Payments To Recoup The Improper Overpayment Refunds

The Proposed Rule provides no avenue for providers and suppliers to cancel the return of funds that the provider or supplier believes, based on later or better information, is not an "overpayment" subject to ACA §6402(d). The potential penalties for not reporting and returning an overpayment, coupled with the short 60-day time period for doing so, likely will result in providers and suppliers erring on the side of caution and returning an overpayment when it is first identified. However, it is foreseeable that providers and suppliers could decide subsequently that a refund was not necessary, so an ability to cancel (or reverse) an unnecessary refund should exist.

There are myriad of situations that could result in this situation, whether it is CMS or its contractors clarifying their guidance in a way that later justifies payment or new information comes to light post-refund that shows the refund was not necessary. **We urge CMS to require contractors to return payments to providers and suppliers when the provider or supplier notifies the contractor that the funds were returned in error and requests a reversal**, provided such requests are made within a reasonable time period (l80 days or less) of the earlier refund. Alternatively, CMS should expand the list of actions in 42 C.F.R. §405.924 that constitute an initial determination, to provide for an appeal right related to a "contractor's acceptance of a refund of an overpayment made in accordance with §401.305."

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The FAH appreciates the opportunity to comment on the Proposed Rule. If you have any questions about our comments or need further information, please contact me or Jeff Micklos of my staff at (202) 624-1500.

Sincerely,