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Electronically Submitted via ProgramIntegrityRFI@cms.hhs.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW Room 445-G
Washington, DC 20201

**Re: Center for Program Integrity Request for Information on the Future of
Program Integrity**

Dear Administrator Verma:

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 hospitals in urban and rural parts of the United States, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. We appreciate the opportunity to provide the Center for Program Integrity, as part of the Centers for Medicare & Medicaid Services (CMS), with our views in response to the *Request for Information on the Future of Program Integrity*.

The FAH provides specific comments on topics related to the Request for Information (RFI), including on provider enrollment, program integrity for value-based payment programs, Medicare Advantage, prior authorization, and provider education. As CMS moves forward with this effort and takes into consideration our comments and others, the FAH urges CMS to take a holistic approach to program integrity that balances the desire to test new approaches with the potential burden placed on beneficiaries and health care providers. Such an approach should include an assessment of the risk any new activities would place on beneficiary access to timely care and payments to providers for services, as well as an assessment of whether these activities would help CMS prevent, detect, or respond to ongoing program integrity concerns.

Provider Enrollment

The FAH appreciates CMS's efforts to identify additional data sources that could help the Agency "identify potentially problematic affiliations" when a provider or supplier enrolls in a federally-regulated program and throughout that provider or supplier's enrollment. The FAH recently provided comments in response to the *Program Integrity Enhancements to the Provider Enrollment Process* Final Rule raising serious concerns about providers' and suppliers' abilities to comply with the requirements to collect, track, and disclose affiliations.¹ These concerns include the sheer breadth of the requirements and the burden it places on providers as well as the infeasibility of even obtaining the data necessary to comply.

Further, in the interest of due process, the FAH strongly suggests that CMS provide notice and a right to respond before imposing a revocation of billing privileges. As a reference, the OIG generally provides a pre-exclusion right to respond (and in the instances in which it does not, notice and opportunity to respond is not necessary or the excluded party has been given another opportunity to respond).² Revocation of Medicare billing privileges (which has the further consequence of revocation of Medicaid billing privileges) is the functional equivalent of an exclusion. Moreover, CMS gives providers and suppliers prior notice with an opportunity for rebuttal for a proposed suspension of payment, recoupment of an assessed overpayment, or offset of overpayment determination.³ The opportunity for notice and response is more dire in a revocation, and the basic notions of fairness dictate that providers and suppliers be given a pre-revocation right to respond.

The FAH encourages CMS to consider this feedback and the FAH's prior comments as the Agency seeks to identify additional data sources going forward.

Program Integrity for Value-Based Payment Programs

Providers who either voluntarily or mandatorily participate in one or more of the value-based payment programs created and implemented by CMS face a myriad of regulatory and legal hurdles to navigate as CMS seeks to operate these new models of care within the existing program integrity framework. While CMS has recently incorporated regulatory waivers into its models, a much more comprehensive approach is required by the Agency to update the existing program integrity requirements for providers to be successful in implementing these new models.

For example, in comments on the now abandoned Episode Payment Models (EPM), the FAH noted the need for revisions pertaining to issues associated with Medicare's coverage and medical necessity policies under the traditional-fee-for-service framework that should be developed and made available under bundled payment programs, the Center for Medicare and Medicaid Innovation (CMMI) models, program integrity activities carried out by Medicare Administrative Contractors (MACs), Quality Improvement Organizations (QIOs), recovery audit contractors (RACs), and various other contractors.

¹ FAH comment letter (Nov. 2019), available at: https://www.fah.org/fah-ee2-uploads/website/documents/Program_Integrity_-_Provider_Enrollment.pdf.

² See 42 C.F.R. § 1001.1301.

³ See 42 C.F.R. §§ 405.372, 405.374, 405.375.

Incentives under these “at risk” bundled payment programs are different than those under the traditional fee-for-service environment, and are aimed at providing more efficient, value-based care. Simply stated, treatment decisions of “at risk” hospitals and their collaborating partners should not be second-guessed and denied on grounds of coverage and medical necessity. We believe that this is unnecessary because hospitals and their collaborating partners will be encouraged and incentivized to coordinate and align treatment decisions across providers, while ensuring that patients receive efficient, high-quality care.

While CMS is correct to consider ways in which these new models may be undermined, it should be equally concerned with protecting program participants from various legal and regulatory risks that are inherent in developing coordinated care arrangements between hospitals, physicians, and post-hospital providers. CMS has been inconsistent and slow to offer waivers of program integrity laws in this arena. Going forward, CMS should timely and consistently provide waiver relief of existing regulations that have the potential to undermine the success of value-based payment arrangements.

Medicare Advantage

The FAH urges CMS to exercise caution when looking to managed care plans under the Medicare Advantage (MA) program for lessons related to program integrity. MA plans’ use of various pre-payment and post-payment “tools” is proliferating, often with significant negative impacts on beneficiary access to timely care and provider payment for services. While some of these tools are meant to ensure program integrity, the concerns detailed below highlight that they are often being used beyond the legitimate scope of program integrity efforts to delay or deny appropriate access to services and/or payments. Such tools are not appropriate in MA, nor are they appropriate for incorporation into other aspects of the Medicare program, and the FAH urges CMS to address these egregious practices.

Unfortunately, our members and the patients they serve have frequently found that MA plans are not properly following Medicare benefit determination and payment rules, leading to inappropriate denials of or delays in enrollees’ accessing care, as well as payments to health care providers. The frequency of inappropriate denials, “downcoding,” and “reclassifications” of medically necessary services is increasing, and the processes for appealing these actions are complex and confusing to beneficiaries and health care providers.

For example, a 2018 Department of Health & Human Services (HHS) Office of Inspector General report highlighted concerns with MA service and payment denials, noting the very low rates of appeals from beneficiaries and providers and the high rates at which MA plans overturn their own denials at various levels of the appeals process.⁴ The OIG report stated, “MAOs may have an incentive to deny preauthorization of services for beneficiaries, and payments to

⁴ HHS OIG, *Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns about Service and Payment Denials*, Sept. 2018, available at: <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>. The report notes that “Medicare Advantage Organizations (MAOs) overturned 75 percent of their own denials during 2014-2016” and that “(t)he high number of overturned denials raises concerns that some Medicare Advantage beneficiaries and providers were initially denied services and payments that should have been provided. This is especially concerning (footnote continued)

providers, in order to increase profits.”⁵ OIG recommended that CMS reduce the incidence of inappropriate denials by: enhancing oversight of MA contracts and taking correcting action; addressing persistent problems regarding inappropriate denials and insufficient denial letters; and providing enrollees with easy-to-understand and easily accessible information about serious MA plan violations. The FAH was pleased to see that CMS concurred with these recommendations and urges the Agency to implement them swiftly.

The FAH is also concerned that MA plans have incentives to reduce payments to providers based on the plan’s determination of the appropriate level of service, often without appropriate review of the medical record documentation (“downcoding”). Because of the limited opportunity to appeal for in-network providers,⁶ MA plans are able to continue this practice with little oversight.

A third example is when MA plans inappropriately reclassify inpatient hospital stays as outpatient “observation” stays (“reclassifications”) despite this being outside a plan’s purview and directly contradicting the Two Midnight Rule. Determining patient status is a clinical decision made by highly-trained medical professionals, yet MA plans have an incentive to utilize this practice to shift costs to enrollees (e.g., greater cost-sharing on outpatient services than on inpatient services) and reduce payment rates below the cost of care provided to the beneficiary. The FAH urges CMS to ensure that MA plans are appropriately following the Two Midnight rule.

Some plans use proprietary non-CMS-endorsed standards to determine coverage for inpatient procedures and inpatient rehabilitation hospital (IRF) coverage. This practice is yet another example of MA plans diverging from Medicare benefit determination and payment rules. The Medicare Inpatient-Only (IPO) list, which is the single, definitive source of guidance as to which procedures must be performed in an inpatient setting in order to be reimbursable by Medicare, is not utilized by some plans. Similarly, many MA plans do not apply CMS’s fee-for-service IRF coverage guidelines, instead using proprietary standards that direct enrollees to less intensive care settings than they need and to which they are entitled.⁷ The use of these proprietary standards creates confusion and administrative challenges for beneficiaries and providers and results in misalignment between the treatment of Medicare beneficiaries under the fee-for-service program and those in an MA plan. The FAH urges CMS to ensure that MA plans are following Medicare benefit determination and payment rules.

Other examples of MA practices that interfere with enrollees’ access to services and/or appropriate provider payments include: delaying provider credentialing to delay payment, inconsistent or unclear audit standards, and delaying acute care discharges, which keeps patients

because beneficiaries and providers rarely used the appeals process.” The report further states that during the two-year period 2014-2016, “beneficiaries and providers appealed only 1 percent of denials to the first level of appeals.”

⁵ *Id.* at pg. 17.

⁶ Unfavorable decisions for in-network providers are considered contractual disputes and are not eligible for appeal to higher levels of review.

⁷ See MMCM, ch. 4 § 10.2. MA enrollees are entitled to – and MAOs must provide – coverage of “all Original Medicare-covered services,” which includes IRF services covered under fee-for-service Part A.

(footnote continued)

in the hospital longer and prevents them from receiving timely access to critical post-acute services. These and the other concerns described above are amplified by the low rate of appeals initiated by beneficiaries and providers, which the OIG found to be 1 percent.⁸ This low rate signifies an “appeals process [that] can be confusing and overwhelming, particularly for critically ill beneficiaries,”⁹ and that requires significant administrative resources and staffing for health care providers. Finally, the appeals processes are not standard across plans, often not automated, and can take months to resolve.

Taken as a whole, these MA practices delay or deny appropriate access to services and/or payments while placing enormous excess administrative costs and burden to the health care system. As noted above, the FAH does not believe these practices are appropriate in MA or elsewhere in the Medicare program and urges CMS to quickly and comprehensively address these and other MA practices that lead to delays or denials of care and/or payments. The FAH also urges CMS to implement the Government Accountability Office’s (GAO’s) recommendation to address fraud risks associated with the MA program.¹⁰ As noted in the GAO report, “most of the agency’s fraud control activities are focused on fraud risks posed by providers,” but ignores other areas of the program, such as how “the inherent design of the Medicare Part C program may pose fraud risks....”¹¹ The GAO goes on to state that:

“CMS had not established preventive fraud control activities in Medicare Part C. Using a fraud risk assessment for Medicare Part C and closely examining existing fraud control activities and residual risks, CMS could be better positioned to address fraud risks facing this growing program and develop preventive control activities.”¹²

Prior Authorization

The FAH appreciates CMS’s desire to improve current prior authorization processes – in both fee-for-service, and particularly in MA, and cautions against expanding the use of prior authorization given the significant concerns detailed below. The current issues should be addressed – and those interventions evaluated for effectiveness – before CMS considers expanding the use of prior authorization within the Medicare program.

Prior Authorization in Medicare Advantage

Our members routinely report delays and inconsistencies with prior authorization processes across MA plans that negatively impact patients’ access to timely medically necessary services, as well as payments to providers for those services. Some of the more common issues with prior authorization include: lack of transparency and clarity regarding the guidelines plans use to evaluate prior authorization requests; delays in plans approving requests; varying authorization and documentation rules across payers and across plans within the same payer;

⁸ HHS OIG Report at pg. 7.

⁹ HHS OIG Report at pg.10.

¹⁰ GAO Testimony Before the Subcommittee on Oversight, Committee on Ways and Means, House of Representatives, *Medicare – Actions Needed to Better Manage Fraud Risks*, July 2018, available at: <https://www.gao.gov/assets/700/693156.pdf>.

¹¹ *Id.* at pg. 15.

¹² *Id.* at pg. 16. GAO also notes that it has previously reported concerns with improper payments in Part C.

lack of ability to rely on prior authorization approvals; and onerous and confusing appeals processes.

For example, different payers – and sometimes different plans within the same payer – use varying proprietary guidelines to evaluate prior authorization requests. These guidelines frequently vary from the well-established guidelines and tools used by providers (e.g., the guidelines used by hospitals to determine appropriate inpatient admissions), leading to conflict between a health care provider’s assessment of a patient’s need for services and the assessment from the patient’s insurance company. When plans deny the prior authorization request, providers struggle to understand why (e.g., based on what guidelines) the request was denied and/or how to correct any real or perceived errors in the request. Sometimes this discontinuity can be addressed without a more formal appeal, but in other instances the patient and/or provider must enter the appeals process.

In addition to delays resulting from initial denials, MA plans are increasingly taking longer to review and adjudicate the initial request. Plans can take multiple days to approve prior authorization for inpatient care, resulting in patients remaining in observation status for an unnecessary, extended period of time. Similarly, providers report delays obtaining prior authorization approval for post-acute care, resulting in patients spending more time than necessary in an inpatient setting, delaying access to critical post-acute care rehabilitation services, and risking patients ultimately being readmitted to the hospital from their home or a less-appropriate post-acute care setting. These delays result in a misalignment in access to timely services for Medicare fee-for-service beneficiaries versus MA plan enrollees.

Providers are also contending with varying authorization and documentation rules across payers and across plans within the same payer. The lack of a single standard across MA plans for prior authorization and documentation rules further contributes to administrative burden and costs for providers and delayed services for beneficiaries.

Even when providers make it through the onerous prior authorization process and receive an approval, they are increasingly finding that plans do not honor that approval at the time of payment. Plan enrollees and the providers who care for them must be able to rely on prior authorization determinations. For example, if a plan provides prior authorization for an inpatient admission or a procedure, the plan should be bound by that pre-service determination for payment purposes.

As discussed above, the low rate of appeals in response to prior authorization denials and other MA practices is concerning and signifies an onerous process. Regarding prior authorizations, the initial denial is often reversed or overturned on appeal, but not without significant effort on the part of the health care provider. This cycle of requests, denials, back-and-forth, and appeals delays patient access to needed services and is unnecessarily burdensome and costly for providers.

Prior to CMS considering any expansion of prior authorization in the Medicare program, the FAH strongly urges the Agency to address the concerns described above. As part of those efforts, the FAH encourages CMS to examine the *Improving Seniors’ Timely Access to Care Act*

of 2019 (H.R. 3107), which would create an electronic prior authorization program, require MA plans to report to CMS their use of prior authorization and approval/denial rates, require plans to adhere to evidence-based guidelines, and require timely prior authorization determinations, to determine actions the Agency can take administratively to improve the current prior authorization process.

Prior Authorization in Medicare Fee-for-Service

Prior authorization in Medicare fee-for-service similarly leads to treatment delays that could jeopardize a beneficiary's health or ability to regain maximum function. Prior authorization also places health care providers in an untenable position of potentially providing needed services immediately, without authorization, and risking payment for all services related to the treatment even if the patient had an urgent need for the medical services. While the provider could request a reconsideration or appeal a denial, this places significant administrative burden on a provider in order to receive payment, even in the most urgent of medical situations.

For example, recently finalized policies in the CY 2020 Outpatient Prospective Payment System (OPPS) Final Rule would allow CMS up to ten days to provide a provisional affirmation for certain services subject to prior authorization. CMS would have up to two days in instances where a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function. In such situations, any responsible health care provider will furnish the needed services immediately, and not wait two days for a response from Medicare, thus risking the provider's payment for a necessary medical service. Even in the former situations, delaying treatment for ten days could lead to patients needlessly suffering from painful and/or debilitating conditions.

In addition, providers are concerned that approved prior authorizations are not guaranteed to be honored at the time of payment. For example, the recently finalized policies in the CY 2020 OPPS Final Rule would allow payment denials for services that received a provisional affirmation based on technical requirements or information not available at the time that affirmation was provided. Approving the service based on the best available information at the time is appropriate, as that is the information upon which the provider based his or her determination of medical necessity. Later denying payment for a service already rendered because of information the provider did not have at the time is patently unfair and inconsistent with applicable medical standards.

Lastly, as the majority of Medicare beneficiaries are covered under the Medicare fee-for-service program, expanding prior authorization to this population would dramatically increase the burden on health care providers – as well as on the MACs. This could lead to a large volume of prior authorization denials and payment denials and a corresponding increase in appeals, straining an already over-burdened appeals process and further delaying patient access to care and timely provider payment.

Provider Education

CMS seeks comment on whether new strategies, tools, or technologies exist that the Agency is not currently using to address and resolve provider education challenges. The FAH commends CMS for its goal of educating providers regarding Medicare coding and documentations requirements, especially early in the process, as well as its ongoing efforts in educating providers and suppliers about Medicare’s requirements through such efforts as the Open Door Forums and publishing Medicare Learning Network educational materials.

As CMS considers existing and new processes for reviewing medical claims and ensuring proper coding and documentation, we urge the Agency to ensure that existing and new requirements are the minimum necessary to ensure proper claims submission and documentation. In addition, the introduction of new medical review and education tools should be streamlined and consistent with the requirements of existing tools and should not be overly burdensome on providers nor introduce additional and concurrent medical reviews for similar claims. CMS also should ensure that provider education efforts help reduce the existing backlog of Medicare appeals, rather than increase it.

In recognizing the importance of its role in educating providers and suppliers about Medicare’s requirements, CMS also discussed the Targeted Probe and Educate (TPE) process, conducted by the MACs and involving significant one-on-one provider education. CMS has noted that a significant percentage of providers and suppliers do not respond timely to the opportunity for TPE. In this regard, we have several recommendations for CMS to improve the TPE process, focusing on clear and consistent administration of the TPE process across MACs:

- *Provide Contact Information for an Individual at the MAC* – There are differences in the level of MAC contact with providers during TPE reviews. We appreciate that some MACs make initial personal contact at inception and maintain a detailed level of communication throughout the review. However, other MACs only send an initial notification letter at the conclusion of the round with no individual contact name. To improve the TPE process and provider timely response, we recommend that CMS consider implementing standards that require the naming of an individual at the MAC for the provider to contact at the inception of the review.
- *Ensure Education Specialists are Familiar with the Topic* – Some MACs direct “education specialists” to conduct the one-on-one education with providers. These individuals often do not have sufficient knowledge of the topic in question or the records that have been reviewed and instead read from a script. We recommend that CMS require MACs to ensure that education specialists are familiar with the topic and records being reviewed to conduct the educational sessions at the conclusion of a review round.
- *Enable Part B Providers to Receive/Submit TPE Record Requests Electronically* – While Part A providers, such as hospitals, are able to receive and submit TPE record requests electronically, this functionality is currently not available for Part B providers, such as physicians. We recognize and appreciate that CMS has provided instruction to its contractors via [Transmittal 907](#) to implement this functionality effective January

2020. We also urge CMS to enforce implementation of the requirements set forth in the Transmittal within the timeframes currently defined.

- *Ensure Uniform Definition of “Payment Error Rate”* – Some CMS contractors and audit officials correctly interpret “payment error rate” to be net of successful appeals, while others interpret “payment error rate” to be all claims initially incorrectly paid. The latter does not account for claims that were successfully appealed and overturned, resulting in some providers with inaccurate and overly inflated “payment error rates” that can lead to additional, inappropriate payment scrutiny and audits. As such, we recommend that CMS ensure that contractors and audit officials interpret “payment error rate” to be net of any successful appeals.
- *Publicly Release Medical Review Rates and Outcomes* – Providers currently do not have access to this information and thus are unable to compare their medical review rates and outcomes with similarly situated providers. We recommend that CMS and the MACs publicly release this data to enable health care providers and researchers to explore patterns among certain providers or provider types that could suggest misunderstandings or misapplications of regulatory requirements.

The FAH appreciates the opportunity to provide comments in response to this RFI and looks forward to continuing to partner with the Agency to improve program integrity. If you have any questions about these comments or need further information, please contact me or Erin Richardson of my staff at 202-624-1500.

Sincerely,