Federation of American Hospitals®

Charles N. Kahn III
President and CEO

January 27, 2025

Via electronic submission at *http://www.regulations.gov*

Mr. Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-4208-P, Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly: Proposed Rule (Vol. 89, No. 237), December 10, 2024.

Dear Acting Administrator Wu:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The FAH appreciates the opportunity to submit comments to Centers for Medicare & Medicaid Services (CMS) regarding the above-referenced *Proposed Rule on Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly* published in the Federal Register (89 Fed. Reg. 99,340) on December 10, 2024. The Medicare Advantage (MA) program provides tremendous opportunities for the delivery of high-value care, and the Proposed Rule contains some critical codifications, clarifications, modernizations, and improvements that will provide a platform for a more robust, value-

oriented, transparent, accountable, and efficient MA program. The FAH thus urges finalization of many of these proposals, as further detailed below.

BALANCING INNOVATION WITH APPROPRIATE GUARDRAILS FOR ARTIFICIAL INTELLIGENCE

(Part III.J, 42 CFR §§ 422.2, 422.112)

The FAH agrees with CMS that artificial intelligence (AI) and related technology is rapidly evolving, as is its application in healthcare.[1] Although there are opportunities for AI to allow for innovation and efficiency in the payment, management, and delivery of health care services, AI tools' lack of transparency poses inherent risks that should be affirmatively addressed with appropriate guardrails. CMS has already taken steps to ensure the responsible use of AI in the MA program, emphasizing that "An MA organization cannot avoid or evade responsibility for compliance with MA regulations and the MA contract by using . . . automated systems and the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all regulations and terms and conditions of the MA organization's contract with CMS."[2] In the February 2024 HPMS Memo, CMS properly reminded MA organizations that AI "cannot be used to shift the coverage criteria over time" and that coverage determinations must be based on the patient's individual circumstances.[3]

Recognizing the need to more broadly address the proper uses of AI and automated systems in the MA program, the Proposed Rule would adopt a definition of "automated system" in § 422.2 and would expressly confirm that AI or automated systems (if any) must be used in a manner that preserves equitable access to MA services under proposed § 422.112(a)(8)(ii). ***The FAH commends CMS' commitment to ensuring that MA organizations "provide all enrollees, without exception, equitable access to services, including when MA organizations use AI or other automated systems to aid their decision-making," and we urge CMS to take care to ensure the use of AI does not erode the MA system by improperly limiting MA enrollees' access to high-value care.***[4] Our members have generally reported concerns with delays, inconsistencies, and inappropriate denials by MA organizations implementing utilization management and notification processes for both emergency and nonemergency care, as well as for discharges to post-acute care settings. Properly deployed and trained, AI has the potential to reduce these problems by, for example, identifying manual review errors and system errors and other root causes of inappropriate denials and errors. But AI also has the potential to worsen existing system problems, to the detriment of enrollees, providers, and taxpayers. It is therefore critical to ensure that any AI tools implemented by MA organizations do not exacerbate these disparities between MA enrollees and traditional Medicare beneficiaries or lead to inequitable outcomes.

---

[1] 89 Fed. Reg. at 99,397–8.

[2] *Id.* at 99,458; *see also* Memorandum from CMS to All Medicare Advantage Organizations and Medicare-Medicaid Plans, Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F) (Feb. 6, 2024), *available at* https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-2-february-5-9 (hereinafter, February 2024 HPMS Memo).

[3] February 2024 HPMS Memo, pp. 2–3.

[4] 89 Fed. Reg. at 99,397.

To that end, we encourage CMS to require increased and more robust monitoring of any AI tool employed by an MA organization so that there is always a human "in the loop" overseeing and correcting for inequities resulting from AI systems. In particular, due to these potential biases in AI design and the risk that the use of AI will devalue the MA program, ***the FAH encourages CMS to consider more robust requirements for MA organization oversight of any AI tool deployed, such as requiring active and constant supervision of their use to inform any clinical decision-making***. Periodic review of otherwise opaque AI processes may not be sufficient for MA organizations to adequately ensure that they can maintain compliance with section 1852(b) of the Act or § 422.110(a), and, due to the rapidly changing nature of the AI industry, enrollees may be at risk of significant inequities and resultant harm without more robust oversight and compliance requirements.

PROMOTING CONSISTENCY IN BEHAVIORAL HEALTH BENEFITS
(Part III.L, 42 CFR §§ 417.454, 422.100)

The FAH supports efforts to enhance MA enrollees' access to behavioral health services, including the proposal to limit cost-sharing for these services consistent with Traditional Medicare. Addressing excessive cost sharing for behavioral health services is an important MA program resiliency measure that would promote robust network participation by high-quality behavioral health providers and better meet the needs of MA enrollees. Moreover, this action falls squarely within the Secretary's statutory authority under section 1852(a)(1)(B)(iv)(VIII) of the Act to identify services (in addition to chemotherapy administration services, renal dialysis services, and skilled nursing care) where it is appropriate to limit cost-sharing levels to those under Traditional Medicare. Therefore, the FAH urges CMS to implement the behavioral health cost-sharing limits as proposed. Like CMS, the FAH does not believe that this proposal will produce immediate and drastic changes in utilization. Therefore, the proposal can and should be implemented for contract year 2026 without a transition period or other delays that would impede enrollee access to behavioral health services.

In projecting the potential impact of this proposal on plans and enrollees, CMS excluded D-SNPs from its quantitative analysis, noting that states cover Medicare cost sharing for many dually eligible enrollees.[5] In doing so, however, CMS properly noted that the proposal would "have a beneficial effect on access to care for dually eligible individuals by increasing revenue for behavioral health providers in any instances in which states do not cover the full cost sharing amounts on their behalf."[6] Many states pay nothing at all for the Medicare cost-sharing obligations of qualified Medicare beneficiaries (QMBs) by virtue of the "lesser of" rule. When QMBs are enrolled in Original Medicare and Medicaid fails to make payment for Medicare cost-sharing amounts, the provider can partially offset its losses by claiming these unpaid amounts as Medicare bad debt. But, when a QMB enrolls in an MA plan, their provider might not receive any payment for the unpaid cost-sharing obligation because MA organizations are not statutorily compelled to cover providers' bad debts, even in part. This is true even though CMS includes payments for bad debts in its capitated payments to MA organizations. As a result, providers are often financially penalized for serving dually eligible beneficiaries enrolled in MA plans (including D-SNPs) because the total payment to the provider is effectively reduced by the cost-

[5] *Id.* at 99,413.
[6] *Id.*

sharing amount. The FAH, therefore, continues to encourage CMS to further explore policy options that will protect providers from systematic underpayments attributable to unmet MA cost-sharing obligations.

CMS' proposal to limit cost sharing for behavioral health services would thus mitigate the untenable financial risk placed on behavioral health providers that serve dually eligible MA enrollees, as well as reduce the transaction costs and burdens associated with billing and collecting larger cost-sharing amounts from MA enrollees more generally. Removing or reducing these significant disincentives for behavioral health providers to participate in MA would thus promote robust MA networks that include high-quality behavioral health providers.

UTILIZATION MANAGEMENT TRANSPARENCY
(Part III.M, 42 CFR § 422.137)

The FAH strongly supports the proposed amendments improving the MA utilization management committee's analysis of prior authorization impacts at 42 C.F.R. § 422.137(d)(6)(iii) as a pragmatic and minimally burdensome process improvement that will provide needed transparency around crucial plan performance data. The FAH strongly supports focused and productive transparency measures that provide high value to Medicare consumers, and we have long been concerned that aggregated reporting across service lines by MA organizations obscures probative and relevant data. At present, § 422.137(d)(6)(iii) requires the MA organization to aggregate data for all items and services when analyzing the impact of its prior authorization practices, and thus it is only aggregated data that is made public under § 422.137(d)(7). The item- and service-level data called for in the Proposed Rule is essential to the MA organization's internal evaluation of its plans' handling of standard and expedited prior authorization requests, both in terms of timing and outcomes, allowing the MA organization to identify plan level-gaps and implement needed improvements. As CMS observes, "information relevant to this analysis and corresponding report is routinely collected in plan systems for each covered item and service, and therefore the data required for this analysis should be readily available for plans." 89 Fed. Reg. at 99,502. As a result, the proposal to shift from aggregated to unaggregated data is minimally burdensome for MA organizations.

The proposed shift from aggregated to unaggregated data in the prior authorization analysis would not only improve the utility of the analysis to the MA organization, it would also, by virtue of the associated public report of machine-readable data under § 422.137(d)(7), significantly improve transparency with respect to plans' track records on prior authorization activities. As the Office of Inspector General (OIG) has observed, prior authorization denials have significant adverse impacts even when such denials are overturned, including the "administrative burden for beneficiaries, providers, and MAOs."[7] Thus, prior authorization transparency allows consumers to better compare MA plans and make informed enrollment decisions, while also providing regulators and provider stakeholders with necessary information on MA organizations' denial records and compliance with coverage requirements. The OIG and others have acknowledged that item- and service-level prior authorization data is essential to the

[7] U.S. Department of Health and Human Services, Office of Inspector General, Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care, OEI-09-18-00260 (Apr. 2022), *at* https://oig.hhs.gov/documents/evaluation/3150/OEI-09-18-00260-Complete%20Report.pdf.

evaluation of plan performance because the aggregation of data obscures data with respect to item and service types that are disproportionately denied by MA plans. In its April 2022 report on MA organization denials of prior authorization requests, the OIG noted that certain items and services (*e.g.*, advanced imaging services and inpatient rehabilitation facility services) were disproportionately impacted by inappropriate prior authorization denials.[8] As a result, the OIG recommended improvements in CMS' MA oversight, including the examination of particular service types (rather than aggregated denial data) in CMS audits. The Proposed Rule, by requiring MA organizations to internally analyze item- and service-level data through its utilization management committee and make its results public, thus represents a pragmatic and appropriate transparency initiative that is consistent with OIG conclusions and recommendations.

PROMOTING INFORMED CONSUMER CHOICE THROUGH MEANINGFUL NETWORK ADEQUACY REVIEWS
(Part III.N, 42 CFR § 422.116)

The FAH strongly supports CMS' proposal to conduct network adequacy reviews at the plan benefit package level. We agree that this level of review provides a "more accurate portrayal of an enrollee's experience" by evaluating whether each beneficiary served by the MA organization in the service area will have access to an adequate provider network.[9] Plan benefit package-level reviews will allow consumers to prioritize their own preferences when selecting among MA plans, focusing on dimensions of cost, quality benefit design, and the presence of particular providers in the network, all without needing to worry that the plan may not satisfy basic network adequacy requirements.

Moreover, this approach offers a critical tool to address a significant concern: networks appearing adequate in provider directories but proving inadequate in practice due to the use of "sub-networks." This deceptive practice undermines consumers' ability to shop for plans based on the presence of specific providers identified in their directories. As noted in our prior comments, MA organizations often contract with organizations that furnish covered services through sub-networks, which restrict enrollees' access to the full range of providers listed in the directory. The contractors using these subnetworks are often affiliated with their own contracted or employed physician or provider groups. MA organizations' sub-capitation arrangements create a financial motivation for downstream organizations to direct care to a particular physician or provider group. As a result, these provider groups often become the enrollees' *de facto* provider network notwithstanding the MA organization's presentation of its full network in the provider directory and the Health Service Delivery (HSD) tables used in network adequacy reviews. This practice creates confusion among MA enrollees who may have reviewed the plan's network information in an effort to ensure in-network access to their preferred physicians, hospitals, and other providers, only to realize later that a downstream organization will discourage them from accessing particular providers. Ultimately, the downstream organization's sub-network itself may not satisfy the network adequacy standards established by CMS in accordance with section 1852(d)(1) of the Social Security Act. Focusing review at the plan benefit package level will provide a more accurate reflection of enrollee experience and expose these hidden network deficiencies, particularly in post-acute care settings where timely access is

[8] *Id.*
[9] 89 Fed. Reg. at 99,426.

crucial for patient well-being and efficient utilization of acute care resources. We applaud CMS for prioritizing this more granular review process to ensure beneficiaries have genuine access to the care they need.

We also note that current network adequacy standards can also fail to capture the realities of post-acute care access to ensure that each MA organization offers a sufficient number of in-network post-acute beds. Minimum bed number requirements under 42 C.F.R. § 422.116(e)(2)(iii) can be met with a single in-network skilled nursing facility (SNF), offering little incentive for MA organizations to develop robust post-acute networks. We reiterate our previous recommendation that CMS establish minimum network adequacy requirements for long-term care hospitals (LTCHs) and inpatient rehabilitation facilities (IRFs) separately in addition to SNFs and implement measures to ensure timely discharges to appropriate post-acute settings. These steps are essential to address the current gap between theoretical network adequacy and actual access to timely, accessible, high-quality post-acute care.

We also support the proposal to codify the existing network adequacy exception rationales, with the proposed narrowing of acceptable reasons for exceptions. Eliminating the rationale that a "provider does not contract with any organization or contracts exclusively with another organization" is a positive step towards ensuring broader provider participation and preventing MA organizations from circumventing network adequacy requirements.[10] This change will encourage MA organizations to actively work with a wider range of providers and build more comprehensive networks that truly serve the needs of their enrollees. We believe this narrowing of exceptions will promote consumer choice and improve beneficiary access to care.

Finally, and as discussed in previous comments, we continue to urge CMS to consider incorporating network adequacy and stability into the Star Ratings Program. A metric reflecting an MA plan's historical performance on network adequacy and stability would provide valuable transparency for enrollees seeking to make informed plan choices and use quality-based competition to incentivize the MA market to meet enrollees' demands for robust and reliable networks.

PROMOTING COMPETITION AMONG PLANS BY PUBLISHING PROVIDER DIRECTORY DATA ON MEDICARE PLAN FINDER

(Part III.P, 42 CFR §§ 422.111 and 422.2265)

The FAH strongly supports CMS' attention to network adequacy and its proposals to improve consumers' ability to make meaningful comparisons of their choices when shopping for an MA plan. ***In particular, we strongly support the proposal to require MA plan provider directory information be published on Medicare Plan Finder (MPF) and to require an MA organization to attest that the information being submitted is accurate and consistent with data submitted to comply with CMS' MA network adequacy requirements at § 422.116(a)(1)(i).*** The FAH applauds this action as an important step to foster MA organization network transparency and promote competition among MA organizations, so that Medicare beneficiaries

[10] *See id.* at 99,425.

contemplating enrollment in MA are as fully informed as possible regarding the networks available to them.

The FAH also supports the current proposed requirement that the MA "organization attest that the information being submitted to CMS/HHS under this new requirement is accurate and consistent with data submitted to comply with CMS' MA network adequacy requirements at § 422.116(a)(1)(i)." 89 Fed. Reg. at 99,432. The FAH agrees with CMS' recognition that provider data changes frequently, and that it is critical that information submitted on provider network adequacy is accurate when made available in MPF. While we recognize that it may be burdensome on MA organizations to provide up-to-date provider network data, given the importance of this information in promoting informed beneficiary plan choice and increasing access to care, the FAH supports attestation being required at least annually, if not more frequently.

ENHANCING REVIEW OF MARKETING & COMMUNICATIONS
(Part III.Q, 42 CFR §§ 422.2260, 423.2260)

Although the FAH generally supports CMS' proposal to eliminate the content standard from the definition of "marketing" under 42 C.F.R. §§ 422.2260 and 423.2260, we are concerned that the change as proposed could unwittingly and inappropriately chill patient-provider communications. ***We urge CMS to include an express carveout for all provider-patient communications to avoid inadvertently hindering the flow of essential information between providers and their patients. This carveout should ensure that providers can continue to discuss appropriate healthcare options and coverage with their patients without fear that those communications might be considered marketing and without needing to first secure review by CMS or MA organizations.*** Open communication between providers and patients is vital for shared decision-making and ensuring patients receive quality care. A clear carve-out for provider-patient communications will protect this vital relationship and ensure that beneficiaries continue to receive the personalized guidance they need to make informed healthcare decisions.

MEDICAL LOSS RATIO
(Part III.T, 42 CFR §§ 422.2401, 422.2420, 422.2430, 422.2450, 422.2452, 422.2454, 422.2460, 422.2480, 422.2490, 423.2401, 423.2420, 423.2430, 423.2450, 423.2452, 423.2454, 423.2480, 423.2490)

The FAH commends CMS for its proposed modifications to the Medical Loss Ratio (MLR) reporting requirements and the addition of requirements based on MLR audit examinations in Medicare Parts C and D. The FAH recognizes the importance of a robust and transparent MLR program in ensuring the financial integrity of the MA program, and ultimately, ensuring that it provides enrollees with high-value coverage. Pursuant to section 1857(e)(4) of the Act, MA organizations are required to return excess MA funds if they fail to achieve an MLR of at least 85 percent. Meaningful MLR requirements thus provide MA enrollees and taxpayers with assurances that the MA program is using Medicare Trust Fund dollars and premiums to provide real value rather than diverting funds to inefficient administrative expenses and profits. The FAH thus generally supports the proposals to codify existing guidance and requirements, implement MLR requirements for the MA program consistent with those in place for the commercial and Medicaid market, and otherwise improve the effectiveness of the MA MLR.

In the decade following the initial development of MLR reporting, we have seen a significant increase in vertical integration among MA organizations, with MA organizations acquiring and controlling a growing number of providers. These market trends threaten to jeopardize the utility of the MLR and the public confidence it inspires in the MA program insofar as the MLR requirements are not modernized to address vertical integration and transfers between related entities. The Proposed Rule and the included Request for Information (RFI) rightly focus on these market trends and the resulting need for MLR modernization. As detailed further below, the FAH supports MLR modernization to account for increasing vertical integration in the MA market.

Incentive and Bonus Arrangements (42 C.F.R. § 422.2420(b)(2)(xi)). The FAH generally supports the intent of the proposed amendment to § 422.2420(b)(2)(xi), which targets incentive and bonus payments to related parties by requiring payments be tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards in order to be included in the numerator. But the FAH recommends that CMS consider a more targeted approach that maintains the current rule for incentive and bonus payments to unrelated parties and imposes the additional requirements for payments to affiliated providers, including those under common ownership or control with the MA organization. There is little reason to suspect that a bonus or incentive payment made in an arm's length transaction to an unrelated provider is not properly based on the value furnished by the provider. In contrast, when such payments represent transfers to a related entity, those payments may be designed to eliminate an MLR rebate obligation rather than reward high-value care. By limiting the additional requirements to these high-risk, related-party transfers, the FAH believes that CMS would maximize the impact of the bonus and incentive payment rule while minimizing burdensome reporting and recordkeeping for low-risk incentive and bonus payments.

Request for Information on MLR and Vertical Integration. Over the past decade, the FAH has become concerned that transfers from MA organizations to related parties might obscure actual spending on profits and administrative expenses by the integrated system as a whole. The proposed amendment to § 422.2420(b)(2)(xi) could be a useful component to addressing these concerns, particularly if focused on transfers to related parties. But MA organizations may also be incentivized to make claims payments to providers under common ownership or control claims that exceed fair market value. Should related party transfers in vertically integrated MA organizations be left unchecked, it may diminish public faith in the program, eliminate competition from unintegrated MA organization, and reduce financial stability in the MA market. The FAH thus strongly supports transparency and accountability with respect to MA organization payments to related providers in vertically integrated systems, as well as MLR reforms that distinguish between *bona fide* claims payments to related providers and related party transfers that reduce MLR rebate payments without providing programmatic value.

ENHANCING RULES ON INTERNAL COVERAGE CRITERIA
(Part III.U, 42 CFR § 422.101)

The FAH strongly supports continued fidelity to Congress's statutory mandate in section 1852(a)(1) of the Social Security Act (42 U.S.C. § 1395w-22) that MA plans provide Original Medicare benefits to their members. The recent modernization of § 422.101 was a critical

measure to address MA misconceptions with respect to this fundamental statutory requirement, and the FAH strongly supports CMS' efforts to continue identifying and addressing common misunderstandings so that the MA program operates to provide real value to MA members. In relevant part, the Proposed Rule would make useful clarifications and refinements to the rules around MA organizations' internal coverage criteria that will better ensure that MA members receive basic benefits that MA organizations are paid to provide, consistent with Congress' mandate.

Automatic Denials Prohibited. Proposed § 422.101(b)(6)(iv)(B) is a prime example of a useful clarification targeting unlawful coverage denials. This provision would prohibit any internal coverage criterion "used to automatically deny coverage of basic benefits without the MA organization making an individual medical necessity determination." The FAH strongly supports this proposal and agrees that "[i]nternal coverage criteria that neither consider[] the individual medical necessity of the patient nor the clinical effectiveness of the care would be inconsistent with sections 1862 and 1852(g)(1)(A) of the Act."[11]

Interpretive and Supplementary Criteria. With respect to the proposed revisions to the first sentence of § 422.101(b)(6)(i)(A), the FAH agrees that "general provisions" in the current regulation "encapsulate[s] all forms of applicable Medicare coverage and benefit rules that exist in statute, regulation, NCD, or applicable LCD."[12] The FAH likewise strongly supports the intent to make it "explicitly evident that internal coverage criteria may only be used to supplement or interpret already existing content within these Medicare coverage and benefit rules" and "cannot be used to add new, unrelated" coverage criteria for an item or service that has existing, but not fully established, coverage policies.[13] We are concerned, however, that the use of the word "plain language" could be misunderstood as suggesting that Medicare coverage criteria should be interpreted based on plain language alone without consideration of context and CMS guidance. Instead, the FAH recommends that the regulatory language be revised to expressly state that new, unrelated coverage criteria cannot be applied under this provision as follows:

> Additional, unspecified criteria are needed to interpret or supplement the ~~**plain language of**~~ applicable Medicare coverage and benefit criteria in order to determine medical necessity consistently. **Such additional criteria must only supplement or interpret applicable Medicare coverage and benefit criteria and must not add new, unrelated coverage criteria.**

The FAH is similarly concerned that the reference to "plain language" in proposed § 422.101(b)(6)(ii)(C) could likewise be misconstrued, and instead recommends stating that "the MA organization must **specifically** identify the ~~**plain language of**~~ applicable Medicare coverage and benefit criteria that are being supplemented or interpreted."

Balance of Harms and Benefits. Under existing § 422.101(b)(6)(i)(A) and (ii)(C), MA organizations must demonstrate that supplementary or interpretive criteria "provide clinical

[11] *Id*. at 99,459.
[12] *Id.* at 99,456.
[13] *Id*.

benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services" and must make public an explanation of how such criteria "provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services." The FAH strongly supports this requirement—including its transparency elements—but, like CMS, is concerned by the extent of MA organizations' failure to explain the balance of clinical harms and benefits. In particular, the FAH agrees with CMS' observation that there are "numerous instances of MA organizations simply and baldly stating that their internal coverage criteria provide clinical benefits that are highly likely to outweigh any clinical harms."[14]

The FAH supports CMS efforts to ensure that each internal coverage criterion used by an MA organization does not clinically harm members by adding the express prohibition on criterion that do not have any clinical benefit at proposed § 422.101(b)(6)(iv). It is inappropriate for an MA organization to use an internal coverage criterion that does not have any clinical benefit, and this prohibition should thus apply to all internal coverage criteria, not just internal coverage criteria authorized under § 422.101(b)(6)(i)(A).

The FAH, however, urges CMS to revise the proposed prohibition to make clear that there must be actual evidence of a clinical benefit, consistent with the threshold requirements under § 422.101(b)(6), and that such clinical benefit must offset any potential harms. In particular, the FAH recommends revising proposed § 422.101(b)(6)(iv)(A) to read as follows: "The current evidence in widely used treatment guidelines or clinical literature either does not demonstrate that the criterion has a clinical benefit or does not demonstrate that such benefit outweighs any clinical harms, including from delayed or decreased access to items or services."

In addition, the FAH strongly supports retaining the requirement at existing § 422.101(b)(6)(ii)(C) that the MA organization make public its explanation of how the additional criteria provide such clinical benefits. It is the FAH's understanding that the disclosure requirements under § 422.101(b)(ii)(A) and the first sentence of § 422.110(b)(ii)(C) would continue to require that the MA organization make public a summary of the evidence and sources that were considered and an explanation of the rationale with respect to the clinical benefit(s) of each criterion, such that the deletion of the clinical benefits language from § 422.101(b)(ii)(C) would not lessen transparency around internal coverage criteria. In order to make this clear, however, the FAH recommends expressly adding "including evidence of clinical benefit" to the end of the first sentence in proposed subparagraph (A) and subparagraph (C).

NCD and LCD Flexibility. The FAH also supports the proposed minor changes to § 422.101(b)(6)(i)(B). This provision delineates those circumstances in which Medicare coverage criteria are not fully established because an applicable NCD or LCD provides the flexibility to cover or not cover an item or service beyond the specific indications listed in the NCD or LCD. The FAH supports the proposed refinements to this language, which consist of the addition of the word "applicable" before "LCDs" and "discretionary" before "coverage" as minor edits confirming the narrow scope of this provision.

[14] *Id.* at 99,456–57.

The FAH also appreciates CMS educating MA organizations through the Proposed Rule regarding the significant differences between LCDs and Referenced Local Coverage Determination articles.[15] Referenced Local Coverage Determination articles do not establish Medicare coverage criteria and are thus not referenced in 42 C.F.R. § 422.101(b). And because these articles do not meet the standard of "current evidence in widely used treatment guidelines or clinical literature," these articles cannot be adopted by an MA organization as internal coverage criteria under 42 C.F.R. § 422.101(b)(6). It is therefore unlawful for an MA organization to use or apply a Referenced Local Coverage Determination article when making coverage decisions on basic benefits.

Definition of Internal Coverage Criteria. The FAH strongly supports the proposed § 422.101(b)(6)(iii), which would expressly codify the definition of "internal coverage criteria" consistent with the CY 2024 MA Final Rule. The FAH understands that the requirements under § 422.101(b)(6) apply to all policies, measures, tools, or guidelines[16] (*e.g.*, InterQual criteria), however designated by the MA organization, that are applied to basic benefits but not expressly stated in applicable Medicare statutes, regulations, NCDs, LCDs, or CMS manuals and that an MA organization cannot apply a policy, measure, tool or guideline to a basic benefit that is not so expressly stated unless it complies with the requirements of § 422.101(b)(6). As CMS correctly notes, "[e]very instance where the plain language of a Medicare coverage rule is interpreted or supplemented is considered internal coverage criteria, and each instance must be based on current evidence in widely used treatment guidelines or clinical literature and must be publicly accessible" in accordance with these requirements.[17] Although we believe that this is clear under existing law, the FAH's members have reported MA organizations taking inconsistent positions, and we believe therefore that it is appropriate to codify the express definition as proposed.

The FAH also agrees with CMS' established interpretation of its regulation with respect to internal coverage criteria built into an algorithm or software tool, as set forth in the February 2024 HPMS Memo (p.2) and the Proposed Rule. CMS correctly states, "An MA organization cannot avoid or evade responsibility for compliance with MA regulations and the MA contract by using . . . automated systems and the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all regulations and terms and conditions of the MA organization's contract with CMS."[18] As CMS has made clear, MA organizations cannot use any automated system that applies criteria that are not expressly stated in applicable Medicare statutes, regulations, NCDs, LCDs, or CMS manuals and do not meet the substantive and procedural requirements for internal coverage criteria under § 422.101(b)(6).

Transparency. The FAH appreciates CMS' proposal to add more structure and detail to the public accessibility requirements to ensure that this information is made available in a manner that is standardized and easy to follow. Transparency around internal coverage criteria allows enrollees to make informed choices on plan selection and to appeal where coverage is inappropriately denied, and it promotes efficiency by ensuring providers have adequate

[15] *Id.* at 99,458.

[16] As CMS notes, this is appropriately a non-exhaustive list of terminology that a MA organization might use, and the use of other terms would not alter the applicability of the requirements in § 422.101(b)(6).

[17] 89 Fed. Reg. at 99,458.

[18] *Id.*

information about any internal coverage criteria that will be applied to organizational determinations. In addition, transparency provides critical information to legislators and regulators exploring policy initiatives to promote accountability and value-maximization in the MA market.

The FAH supports the following clarifying revisions to proposed § 422.101(b)(6)(ii): (1) changing "internal coverage policies" to "internal coverage *criteria*," so as to maintain consistency across the regulatory language, and (2) changing uses of the plural "criteria" to the singular "criterion" to make it clear that each disclosure obligation applies to each individual criterion. Along similar lines, the FAH supports requiring that the list of sources of the evidence used in the development in a criterion be connected by footnote to the applicable coverage criterion under the proposed amendment to § 422.101(b)(6)(ii)(B). The current practice by some MA organizations of providing a bibliography-style list of sources in a document addressing multiple coverage criteria does not provide patients, regulators, providers, and researchers with necessary information about the evidence considered for any particular criterion.

The FAH also strongly supports the proposed amendments to § 422.101(b)(6)(ii)(A), requiring that each internal coverage criterion be identified and marked as such in the coverage policies of the MA plan. At present, we often see coverage policies that describe both internal coverage criteria and Medicare coverage criteria, blurring the lines between the two. When policies are drafted in that way, it creates unnecessary confusion and can obscure non-compliance with CMS' regulations.

In addition to the refinements to existing transparency measures, the Proposed Rule would add new paragraph (D) to § 422.101(b)(6)(ii), which would require MA organizations to identify each item or service for which there are benefits available under Part A or Part B where the MA organization uses internal coverage criteria when making medical necessity decisions. Like other transparency regulations in the health care space, the proposed disclosure would be in a downloadable and searchable machine-readable file that is available without charge and is directly linked in a .txt file in the root directory of the MA organization's website domain. At present, it is difficult for researchers, policy makers, enrollees, and the public to understand and evaluate the extent to which individual MA organizations apply internal coverage criteria, let alone to compare these practices and the evidentiary backing for these criteria between MA organizations. The machine-readable file described in proposed § 422.101(b)(6)(ii)(D) would fill this transparency gap and would allow policymakers to ensure that MA organizations provide maximum value to the Medicare program.

CODIFICATIONS AND CLARIFICATIONS OF MA ORGANIZATION DETERMINATION RULES

(Part III.V, 42 CFR §§ 422.138, 422.562, 422.566, 4222.568, 422.572, 422.616, 422.631)

We appreciate CMS' identification of significant areas of non-compliance by some MA organizations that create substantial confusion, inappropriately foreclose enrollee appeals, and increase unnecessary transaction costs and burdens on providers. The FAH strongly urges CMS to finalize proposals codifying and further clarifying requirements with respect to organization determinations, as detailed further below. In addition, the FAH strongly supports finalization of the proposed amendment to the reopening rules to address the misuse of later clinical

information to reopen a determination approving an inpatient hospital admission. With the exception of this final proposal, the FAH notes that each of these proposed codifications and amendments would apply to all settings of care, although many of the problems identified in the proposed rule are most prominent with determinations involving hospital and post-acute care settings.

Clarifying Post-Payment Appeals Exception for Network Care (§ 422.562(c)(2)). We share CMS' concerns with the misapplication of existing § 422.562(c)(2) and support the proposed, clarifying amendment to 42 C.F.R. § 422.562(c)(2). Section 422.562(c)(2) bars enrollee appeals of MA organizations' payment determinations concerning care furnished by the MA organization[19] in circumstances where the enrollee has no further liability for those services. FAH members report the same problems identified by CMS—some MA organizations misapply § 422.562(c)(2) to bar appeal of "certain coverage decisions, specifically those related to an enrollee's inpatient admission or level of care" with semantic gamesmanship.[20] As CMS notes, "[t]hese MA organizations often improperly label these adverse coverage decisions as 'contractual denials' or 'payment decisions' even though no request for payment has been submitted and, oftentimes the services are still being rendered at the time of the MA organization's decision."[21] For example, MA organizations have misapplied § 422.562(c)(2) to evade review of coverage determinations relating to the type (including applicable codes), duration, or level of services, including whether hospital services are furnished on an inpatient or outpatient basis or the approved MS-DRG code for an inpatient stay. ***These practices are unlawful under existing § 422.562(c)(2) and section 1852(g)(2) of the Act, and the FAH strongly supports CMS' proposal to further clarify this point by explicitly limiting this exception to appeals of an MA organization's determination on a request for payment.*** In short, under existing law and the proposed amendment, MA organizations cannot evade review of pre-payment coverage determinations, including, but not limited to prior authorization, concurrent review, or retrospective review determinations.

The FAH further reads section 1852(g)(2) of the Act to broadly obligate that MA organizations provide for reconsideration of payment determinations even where the coverage denial therein does not impact enrollee cost sharing, and therefore urges CMS to clarify that § 422.562(c)(2) does not exempt MA organizations from their reconsideration obligations. Under section 1852(g)(2), an MA organization is required to provide for reconsideration of an adverse organization determination "upon request by the enrollee involved," without limitation. To trigger this requirement, the adverse determination must be "a determination that denies coverage, in whole or in part."[22] FAH members report problems with partial denials of coverage that MA organizations claim are not subject to reconsideration requirements under § 422.562(c)(2). For example, an MA organization might decline to fully cover the services furnished and claimed by downcoding the MS-DRG describing those services to a lower MS-

[19] As CMS rightly notes, this exception does not apply to services provided by a non-contracted provider. *Id.* at 99,462 n.253. Thus, for example, if an MA organization downcodes a non-contracted hospital's claim (*e.g.*, paying for a lower MS-DRG rather than the MS-DRG claimed) in a manner that does not impact patient cost-sharing obligations, that is an appealable organization determination and the exception under § 422.562(c)(2) would be facially inapplicable.

[20] *Id.* at 99,462.

[21] *Id.*

[22] Social Security Act section 1852(g)(1)(B), 42 U.S.C. § 1395w-22(g)(1)(B).

DRG. Such downcoding may not impact the enrollee's cost-sharing obligations, but it certainly constitutes a partial denial of coverage such that the MA organization has statutory reconsideration obligations under section 1852(g)(2) if reconsideration is requested. The FAH urges CMS to therefore clarify that § 422.562(c)(2) cannot and does not limit MA organizations' obligations under section 1852(g)(2).

Types of Organization Determinations (§ 422.566(b)(3)). Along similar lines, the FAH strongly agrees with CMS' long-standing interpretation, described in the Proposed Rule, that concurrent review decisions, level of care determinations, clinical utilization review decisions, inpatient authorization denials, and other coverage determinations made before, during, or after the delivery of services constitute organization determinations regardless of the terminology that a MA organization might use.[23] Like CMS, FAH members report issues with MA organizations that fail to comply with their obligations with respect to organization determinations by referring to those determinations as something other than an organization determination, particularly in cases of concurrent or retrospective reviews.[24] For example, FAH members report issues with MA organizations failing to provide enrollees with notice of concurrent review decisions and other organization determinations. The FAH, therefore, greatly appreciates CMS' express and unequivocal statements in the Proposed Rule that these interpretations are erroneous and non-compliant under existing law.[25]

The FAH also strongly supports CMS addressing these "increasingly varied and widespread" non-compliant practices[26] by amending the definition of organization determinations at § 422.566(b)(3) to expressly reference concurrent and post-service review determinations along with pre-service determinations. To be clear, this proposed amendment is not a proposed change in the law but instead is properly considered part of a larger effort to promote compliance with existing law. As existing § 422.566(b)(3) makes clear, an MA organization's refusal "to provide or pay for services, in whole or in part, including the type or level of services" is an organization determination, and this fact is not altered by the terminology used by the MA organization or the timing of the determination relative to the delivery of care.

Prior Authorization Rules and Concurrent or Retrospective Reviews (§§ 422.138(c)). CMS also proposes to make a corresponding change to its prior authorization regulation, expressly referencing concurrent approvals in § 422.138(c). The FAH strongly supports revisions to § 422.138 to address concurrent approvals, but recommends that CMS broadly extend the applicability of § 422.138 to all pre-payment coverage determinations, whether they are made as part of a prior authorization determination, concurrent review, or retrospective (pre-claim) review.

As described in the Proposed Rule, retrospective and concurrent reviews arise in a similar fashion, such that whether a review is retrospective or concurrent is an accident of timing. If the MA organization approves the admission before discharge, it is a concurrent approval, but if it the patient is discharged first, the same determination would be a retrospective approval. Because these are essentially the same types of determinations, the FAH believes that

[23] 89 Fed. Reg. at 99,463.
[24] *Id.* at 99,463–64.
[25] *Id.*
[26] *Id.* at 99,465.

§ 422.138(c) should apply with equal force to both. In addition, the FAH is concerned that limiting the scope of § 422.138(c) to prior authorizations and concurrent approvals would create an inappropriate incentive to delay review and approval of care so that what would otherwise be a concurrent approval converts to a retrospective approval by virtue of the patient's discharge or completion of the course of care. Such delays would burden providers and serve no appropriate purpose. In fact, as noted in the Proposed Rule, the facts and circumstances around the pre-service or concurrent review for inpatient hospital services "will often satisfy the medical exigency standards."[27] The MA organization is thus required to make its determination as expeditiously as the enrollee's health condition requires,[28] and it would be particularly inappropriate for an MA organization to delay an approval until after discharge so that it becomes a retrospective approval rather than a concurrent approval. Because distinguishing between retrospective and concurrent approvals in § 422.138(c) would provide no benefit and would risk harmful delays in organization determinations, the FAH strongly recommends that § 422.138(c) apply to retrospective (pre-claim) approvals as well as concurrent approvals.

In addition, the FAH recommends revising the remainder of § 422.138 to expressly reference both concurrent and retrospective reviews. Subsection (b) sets out the appropriate purposes of prior authorizations, and the FAH does not believe that there is any policy rationale for permitting other pre-payment coverage review processes (*i.e.*, concurrent and retrospective reviews) to be conducted for purposes other than those set forth in subsection (b). Likewise, subsection (a) should be revised to reflect the section's applicability to the full range of pre-payment coverage determinations (prior authorizations, concurrent reviews, and retrospective reviews).

Provider Notice (§ 422.568(b)(1), (d), (f); § 422.572(f); § 422.631(d)(1)). We greatly appreciate CMS' proposal to amend notice requirements to require notice to the physician or provider involved of an organization determination when the provider submitted the request on behalf of the enrollee or when it is otherwise appropriate to provide such notice. This proposal reflects longstanding CMS guidance requiring such notice when the provider submitted the request for the organization determination, and the proposed amendments would establish consistency between the notice requirements for standard organization determinations, expedited organization determinations, and integrated organization determinations.[29] Although many MA organizations generally provide notice to the requesting physician or provider, any instance in which they fail to do so is disruptive for enrollees and unnecessarily burdens the MA delivery system with miscommunications and inefficiencies.

The FAH, however, recommends that CMS make a further corresponding technical amendment to reference the provider in § 422.572(a)(1) and (f) and also expressly define "as appropriate" in the regulatory text in order to minimize the risk of confusion. Existing § 422.572(a)(1) references and proposed, amended subsection (f) would reference the physician involved, without mention of the provider involved, while the corresponding language § 422.568 would reference both physicians and providers. The FAH urges CMS to eliminate this

[27] *Id.* at 99,468.
[28] 42 C.F.R. § 422.572.
[29] 89 Fed. Reg. at 99,467.

discrepancy by adding "or provider" following the reference to the physician in in both subsections (a)(1) and (f) of § 422.572.

The FAH agrees with CMS' proposed definition of "as appropriate," but recommends that this definition be expressly stated in §§ 422.568, 422.572, and 422.631. The preamble to the Proposed Rule makes clear that notice to the physician or provider involved is appropriate in each case where that physician or provider requested the organization determination on the enrollee's behalf. There is no reason that "a provider or physician to whom an enrollee has already entrusted their care or has sought to request coverage for their care, should not receive notice of an organization determination that directly affects such care."[30] Thus, like CMS, the FAH does not find a compelling reason for ever failing to provide notice to the requesting physician or provider. When a provider submits an organization determination request on an enrollee's behalf, its efforts to provide high-quality and timely care can be stymied if the MA organization does not communicate its decisions directly to the provider. Moreover, it is simply inefficient for providers to rely on their patients to share the outcome of an organization determination request. In order to minimize confusion on this point, it would be appropriate to expressly state in the regulatory text that it is always appropriate (and thus required) to provide notice to the submitting provider. For example, the parenthetical language in proposed § 422.568(b)(1) and existing § 422.572(a)(1) might be revised to read "(and the physician or provider **that made the request or, as appropriate, is otherwise** involved~~, as appropriate~~)." In the alternative, the FAH recommends including a regulatory definition of "as appropriate," consistent with the definition in the preamble to the Proposed Rule.[31]

FAH members have also identified issues with the content of provider notices. The approval of some but not all care requested or the approval of care at a place of service different than requested (*e.g.*, outpatient department instead of inpatient hospital) constitutes a partial denial that triggers notice requirements under §§ 422.568, 422.572, and 422.631. MA organizations, however, at times fail to provide notice of such adverse organization determinations by approving certain services and omitting mention of other services or the place of service specified in the request. In these cases, because the organization determination is characterized as fully favorable and no information about appeal rights is provided, the MA organization should be estopped from later asserting that any element of the request for an organization determination was denied. But MA organizations have improperly attempted to later deny coverage of care, particularly inpatient admissions, taking the position that what appeared to be a fully favorable organization determination in fact did not provide approval of certain services or the place of service requested. As a result, these omissions create confusion and uncertainty for enrollees and providers and may impede the delivery of timely, high-value care. The organization determination process is designed to allow enrollees and their providers to confirm coverage for the full scope of services requested at the place of service requested, and omissions cannot and should not be used to subvert the organization determination requirements. The FAH, therefore, urges CMS to clarify that the content requirements for adverse organization determinations continue to apply to partially adverse determinations, and any organization

[30] *Id.* at 99,467.

[31] *Id.* at 99,468 (stating that "as appropriate" means "that notice should be given to the provider or prescriber who submitted an organization determination request on behalf of an enrollee or in other circumstances where it would be in the enrollee's best interest for their provider or prescriber to receive notice of a decision related to an enrollee-submitted request").

determination that is not fully favorable (*i.e.*, approved in all respects) is a partially adverse organization determination.

Modifications to reopening rules (42 C.F.R. § 422.616, § 422.138(c)). The FAH strongly supports CMS' proposal to expressly preclude MA organizations from reopening approvals of inpatient hospital admissions on the basis of clinical information obtained after the initial organization determination. FAH members have reported significant issues with MA organizations miscasting mere hindsight as material evidence supporting good cause for reopening such a determination. For any prior authorization, pre-service, or concurrent review determination, medical record evidence that simply did not exist at the time of the determination is necessarily irrelevant to the determination because the furnishing provider—like the MA organization—must make decisions about the patient's care based on the clinical information available at the time. As new clinical information emerges, the furnishing provider does not have the opportunity to reverse past decisions regarding the patient's care, and the MA organization likewise should not be permitted to reopen its prior determinations using newly obtained clinical information. Thus, even in cases outside the context of an inpatient admission, the FAH does not believe that clinical information that emerges during or after the delivery of approved care and subsequent to the organization determination approving such care could provide good cause for reopening the organization determination. Therefore, the FAH recommends that CMS more broadly limit the use of such later emerging clinical information in good cause reopenings by MA organizations.

Moreover, as explained in the Proposed Rule, the use of post-determination clinical information to reopen the approval of inpatient hospital care is particularly problematic because it is fundamentally inconsistent with the Medicare coverage criteria for inpatient admissions under 42 C.F.R. § 412.3(d)(1) and (3). These criteria, commonly referred to as the Two-Midnight Rule, expressly refer to the admitting physician's *expectations* of the patient's need for hospital care *at the time of admission*. Thus, the admission decision is necessarily made without the benefit of full information about the course of the patient's hospital care. We agree with CMS that "[a]ny additional clinical information obtained after the initial organization determination cannot have the effect of creating a good cause reopening because the determination was made based on what was known by the physician and documented in the medical record at the time of admission."[32] It is simply inappropriate and unlawful under existing regulations for an MA organization to reopen its prior authorization of an inpatient hospital admission based on clinical information obtained during the course of such admission or thereafter. We also agree that a departure from traditional Medicare rules is justified here by virtue of inherent differences between the MA program and Traditional Medicare that necessitate an MA-tailored approach.

Other Appeal Issues—Non-Contracted Appeals. The FAH appreciates CMS' focus on codifying and clarifying rules as set forth above—these efforts rightly prioritize strengthening the MA program, improving enrollee confidence in the MA marketplace, and reducing inefficiencies and practices that excessively and unnecessarily burden providers serving MA enrollees. Along similar lines, the FAH urges CMS to act to address issues with non-contracted provider MA appeals. In particular, our members report deficiencies in the transmission of non-

[32] *Id.* at 99,470.

contracted appeals to the Part C Independent Review Entity (IRE) that could be addressed with appropriate transparency measures, as well as cases where the IRE has not fully applied Medicare fee-for-service coverage and payment criteria to these appeals. The FAH therefore urges CMS to work with its contracted IRE (MAXIMUS) to implement operational improvements that allow the prompt detection and amelioration of MA organizations' deficiencies in the reconsideration process and to provide MAXIMUS with appropriate guidance on the requirement that Medicare basic benefits be provided by MA organizations consistent with Medicare fee-for-service coverage criteria.

The MA IRE regulations are generally designed to ensure that the IRE can undertake each reconsideration with a fulsome record that appropriately presents the provider's reconsideration request and evidentiary record. For example, MA organizations are obligated to send a written explanation and the entire case file to MAXIMUS for reconsideration following its affirmance of an adverse organization determination,[33] and providers are entitled to submit evidence and be satisfied that the case record is complete.[34] In practice, however, the case file is directly transmitted by the MA organization to MAXIMUS without copying the provider, and providers do not otherwise have access to the reconsideration portal for an appeal, such that the provider has no opportunity to detect and cure any gaps in the transmitted appeal and record. In the absence of transparency, the IRE may unwittingly make reconsideration determinations based on an incomplete record, risking erroneous determinations. This in turn increases the costs and burdens for out-of-network providers seeking appropriate payment for the covered benefits they furnished and for the Office of Medicare Hearings and Appeals, which must process appeals that should have been appropriately resolved on reconsideration at the IRE.

The FAH believes that these issues can be appropriately addressed through straightforward transparency and accountability measures that would facilitate the smooth operation of the reconsideration process in accordance with the appeals scheme laid out in CMS' regulations. In particular, providers should be copied on all reconsideration communications between the MA organization and the IRE and should be provided with access to the case file on the IRE's appeals portal and the ability to address gaps in the case file. Transparency on its own will create appropriate incentives for MA organizations to carefully and faithfully transmit the case file, and to the extent that any gaps remain even with this transparency measure, providers would have some opportunity to detect and cure the issue so that the IRE has the benefit of the complete case file—as required by CMS regulations—when making its determination. Additionally, when a provider chooses to be an out-of-network provider it is aware it will not receive the level of volume it would if it were in-network. Providers that choose to be out-of-network should not have to adhere to the same requirements for authorizations, post payments review and audits – FFS rules should apply.

[33] 42 C.F.R. § 422.590(a)(2), (b)(2), (e)(5)

[34] 42 C.F.R. § 422.562(d) (incorporating 42 C.F.R. Part 405); 42 C.F.R. § 405.966 (permitting a provider to present evidence both at the time of and after filing a request for reconsideration); 42 C.F.R. § 405.968(a) (an IRE reviews the evidence and findings upon which the initial determination and redetermination were based, including any additional evidence the parties submit at the IRE Reconsideration stage).

RISK ADJUSTMENT DATA UPDATES
(Part III.I)

With respect to the Part C Risk Adjustment Program, the FAH urges CMS to ensure that risk adjustment payments are made based on data that more accurately reflect the additional expenditures made by MAOs based on members' health status. In particular, the FAH supports limiting MA encounter data to data derived exclusively from paid claims or, in the case of a provider that accepts capitation, provider encounter data. The risk adjustment program is designed to "account[] for variations in *per capita costs* based on health status."[35] At present, we understand that MA organizations include MA encounter data from unpaid, denied and underpaid claims. Such claims do not reflect cost incurred by the MA organization but actually reflect uncompensated care costs incurred by providers. This is particularly true because MA organizations deny claims at significantly higher rates than commercial insurance carriers and self-funded group health plans. Limiting the MA risk adjustment data in this way would not place an undue burden on MA organizations because the current timelines for submission of this data allows adequate time for the prompt payment of claims prior to the initial data submission deadline, and certainly before the final risk adjustment data submission deadline the following year.

IV. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System: Adding, Updating, and Removing Measures (§§ 422.164 and 423.184)

The FAH strongly urges CMS to include the Level 1 Denials Upheld Quality Measure in the Medicare Star Ratings Display. This measure addresses critical issues in the Medicare Advantage program, particularly the systemic misuse of prior authorization processes. Overwhelming evidence demonstrates that plans have weaponized prior authorization, creating unnecessary barriers to care and delaying or denying services that are ultimately deemed medically necessary. While CMS has taken steps to improve accountability in the MA program, including modifying the Level 2 measure in the Star Ratings, more must be done to address the root causes of inappropriate denials at the initial review stage. The Level 1 Denials Upheld measure is a necessary and complementary addition to CMS' existing quality measures, targeting the initial point of care decision-making where beneficiaries are most vulnerable to delays and denials.

Several compelling reasons support the inclusion of this measure. Reports, including those from the HHS OIG, consistently reveal high overturn rates of initial adverse determinations, highlighting systemic flaws in plans' prior authorization processes. These inappropriate denials place undue stress on beneficiaries and their families, create administrative burdens for providers, and delay access to medically necessary care. Displaying this measure in the Star Ratings would incentivize plans to improve their initial determination processes, reducing these unnecessary barriers to care.

The Level 1 Denials Upheld measure also aligns with CMS' focus on improving transparency and accountability in the MA program. As demonstrated with the Level 2 measure already included in the Star Ratings, holding plans accountable for their denial practices fosters

[35] Social Security Act section 1853(a)(3)(A), 42 U.S.C. § 1395w-23(a)(3)(A) (emphasis added).

better decision-making. Moreover, this measure is timely and complements CMS' broader efforts to refine the Star Ratings program, ensuring that beneficiaries have the tools they need to make informed choices about their MA plans.

Importantly, including this measure is feasible and minimally burdensome for plans, as CMS already collects the data required for this measure for internal and regulatory reporting purposes. By leveraging existing data, CMS can ensure that the measure provides meaningful insights without imposing significant additional administrative requirements on plans. Displaying this measure in the Star Ratings would also enhance competition among MA plans, encouraging them to prioritize accurate and fair decision-making to attract beneficiaries.

Key stakeholders have already affirmed this measure's suitability and importance. The consensus-based entity, Battelle, convened the Physician Recommendation Group in January 2024, and the group overwhelmingly supported the measure's inclusion in the Medicare Star Ratings program. Their endorsement reflects a broad consensus among healthcare professionals that addressing initial denials is critical to protecting beneficiaries and ensuring fair and effective plan operations.

CMS' recent focus on updating and refining the Star Ratings Program makes this the ideal time to introduce the Level 1 Denials Upheld measure. Including this measure would provide beneficiaries with vital information about plan performance, helping them make informed enrollment decisions while fostering competition among plans to prioritize fair and accurate coverage determinations. By doing so, CMS would further its commitment to protecting Medicare beneficiaries and ensuring that Medicare Advantage plans operate transparently, responsibly, and with a focus on timely access to care.

The FAH appreciates CMS' continued efforts to improve the MA program and welcomes further engagement to support the inclusion of this critical measure in the Star Ratings Display.

ACHIEVING EFFICIENCIES IN D-SNP PLANS

(Part V, 42 CFR §§ 422.101, 422.107, 422.2267, 423.2267, 422.2, 460.112, 460.70, 423.2267)

The FAH supports pragmatic paper-reduction measures that reduce burdens and maximize efficiencies in the claim submission and payment process for providers who serve dually eligible beneficiaries. As such, the FAH applauds CMS' proposal to establish new Federal requirements for D-SNPs that are applicable integrated plans (AIPs) to: (1) have integrated member identification (ID) cards that serve as the ID cards for both the Medicare and Medicaid plans in which an enrollee is enrolled; and (2) conduct an integrated health risk assessment (HRA) for Medicare and Medicaid, rather than separate HRAs for each program. We agree with CMS' findings that even with CMS' prior actions to advance integrated care for dual-eligible beneficiaries, there remain aspects of care for dually eligible individuals that can be misaligned, confusing, duplicative, or inefficient.[36] CMS' proposal to require integrated member identification cards for both the Medicare and Medicaid plans in which an enrollee is enrolled

[36] 89 Fed. Reg. at 99,485.

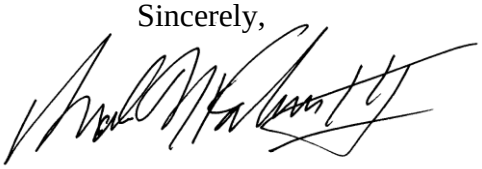
along with integrated HRAs will streamline these programs, improve the consumer experience for dually eligible individuals and will reduce provider and enrollee confusion.

As CMS continues to make efforts to achieve efficiencies across the Medicare and Medicaid programs, the FAH encourages CMS to also consider additional measures to reduce burdens by streamlining the process for providers to receive reimbursement by way of "crossover claims." Presently, many states routinely deny any claims from providers for Medicare cost-sharing amounts by application of the "lesser-of" rule, leading to the incongruous result by which many states pay nothing at all for the Medicare cost-sharing obligations of QMBs. As a result, "providers serving dually eligible MA enrollees are systematically disadvantaged relative to providers serving non-dually eligible MA enrollees, which . . . may negatively affect access to Medicare providers for dually eligible enrollees."[37] Increased enrollment in D-SNP plans will simply compound this systemic disadvantage to providers and exacerbate challenges ensuring access to care for these individuals. The FAH therefore urges CMS to consider possible solutions to this longstanding issue in order to ensure dually eligible individuals can receive care and to eliminate the inefficiency associated with providers' unsuccessful efforts to collect crossover claims.

****

The FAH appreciates the opportunity to submit these comments on these important issues for patients and providers. If you have any questions, please contact me or any member of my staff at (202) 624-1500.

Sincerely,



[37] 87 Fed. Reg. 27704, 27788 (May 9, 2022).