Charles N. Kahn III
President and CEO

February 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: CMS-4201-P, Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications: Proposed Rule (Vol. 87, No. 247), December 27, 2022

Dear Administrator Brooks-LaSure:

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 comment to the Centers for Medicare & Medicaid Services (CMS) about the above-referenced Proposed Rule on Contract Year (CY) 2024 Medicare Advantage (MA) and Part D Policy and Technical Changes and Medicare Parts A, B, C, and D Overpayment Proposed Rule (Proposed Rule). The MA program is an important and growing part of the Medicare program, and the FAH appreciates CMS' proposals geared toward addressing deficiencies in MA enrollees' access to basic benefits.

III.E UTILIZATION MANAGEMENT REQUIREMENTS
§§ 422.101, 422.137, 422.138

The FAH strongly supports CMS' goals of "prohibit[ing] MA organizations from limiting or denying coverage when the item or service would be covered under Traditional Medicare and continue the existing policies that permit MA organizations to cover items and services more broadly than original Medicare by using supplemental benefits" and "ensur[ing] that MA organizations provide equal access to Part A and Part B benefits as provided in the Traditional Medicare Program." 87 Fed. Reg. at 79,499 and 79,502.

As we have described in previous letters, our members report 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. Moreover, as highlighted in the Office of the Inspector General's (OIG's) April 2022 report titled "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care,"[1] MA organizations' utilization management practices can result in denials of care even in circumstances where Medicare coverage criteria had been satisfied such that the beneficiary was entitled to coverage for his or her care. ***The FAH strongly supports CMSs goal of eliminating this disparity and ensuring that MA beneficiaries receive full coverage for the basic benefits to which they are entitled.*** This work is particularly important to support CMS' goal of promoting health equity when MA beneficiaries disproportionately include historically underserved populations as compared to Traditional Medicare beneficiaries. We write to offer suggestions on how to achieve these goals more effectively, including through revisions to the proposed regulatory changes and through the adoption of oversight and enforcement mechanisms targeting MA organizations' utilization management programs in particular.

III.E.2 Coverage Criteria for Basic Benefits (42 C.F.R. § 422.101)

Medicare Coverage Criteria (Proposed Revisions to 42 C.F.R. § 422.101(b)(2))

The FAH strongly supports the proposal to revise 42 C.F.R. § 422.101(b)(2) to incorporate references to specific Medicare coverage criteria that MA organizations must apply. ***In particular, the FAH applauds the proposed amendments to subsection (b)(2) explicitly referencing key Medicare coverage criteria, including the two-midnight rule for inpatient hospital care and the Medicare coverage criteria for skilled nursing facility (SNF) care, Home Health services, and Inpatient Rehabilitation Facility (IRF) admissions.*** FAH members have reported that their MA-enrolled patients disproportionately encounter barriers flowing from MA organizations' failure to adhere to Medicare coverage criteria. Too frequently, MA organizations incorrectly characterize the Medicare coverage criteria (including those set forth in the proposed regulatory text) as "payment rules" that can be ignored and instead apply their own variable and subjective internal coverage criteria, denying coverage for care that would be covered under Traditional Medicare. In light of this experience, the express references to 42 C.F.R. § 412.3, 42 C.F.R. Part 409, and 42 C.F.R. § 412.622(a)(3) in the proposed revisions to 42 C.F.R.

[1] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

§ 422.101(b)(2) are critical to clarify MA organizations' obligations and promote equitable beneficiary access to basic benefits.

With respect to inpatient hospital admissions in particular, the FAH agrees that 42 C.F.R. § 412.3 sets forth well-established Medicare coverage criteria for inpatient admissions. Under the two-midnights component of this rule (paragraph (d)(1)), the critical criterion is whether "the admitting physician expects the patient to require hospital care that crosses two midnights."[2] As the FAH has previously shared with CMS, there has been and continues to be a significant trend among MA plans of denying authorizations for inpatient admissions and reclassifying them as outpatient observation stays based on a variety of plan-specific standards, notwithstanding the fact that determining a patient's status is a clinical decision that must be made by the physician treating the patient. We are pleased that this proposed regulation would eliminate the unnecessary confusion caused by MA organizations' inconsistent application of or disregard for the two-midnight rule.[3]

The FAH likewise supports the proposed inclusion of an explicit reference to the Medicare coverage criteria for inpatient rehabilitation facility (IRF) admissions at 42 C.F.R. 412.622(a)(3).[4] MA organizations' failure to provide coverage for IRF admissions in accordance with Medicare coverage criteria produces a significant and inequitable disparity in beneficiary access to timely and appropriate IRF care. In fact, the April 2022 OIG Report identifies post-acute care in SNFs and IRFs as one of the three most prominent service types among the denied requests for MA organization prior authorizations and payments that met Medicare coverage rules.[5] As the OIG explained, "To reduce their costs, MA organizations may have an incentive to deny more expensive services, such as inpatient rehabilitation facility stays, and/or require that beneficiaries receive less expensive alternatives."[6] Unchecked, this incentive places MA beneficiaries' IRF benefits in critical jeopardy, and the FAH strongly supports the proposed addition of an explicit reference to IRF coverage criteria to 42 C.F.R. § 422.101(b)(2).

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[2] In addition, 42 C.F.R. § 412.3(d) provides for coverage of inpatient admissions for surgical procedures on the inpatient only list as well as inpatient admissions not expected to cross two midnights based on the clinical judgment of the admitting physician and supported by the medical record support.

[3] Moreover, it is the FAH's understanding that, with the proposed amendment, MA organizations would be required to ensure that MA plan contracted physicians follow the two-midnight rule in determining patient status. This would address the problem of contracted physicians with financial incentives from the MA plan changing the admission status before discharge (even where the stay crosses two midnights) to reduce the payment for care and deprive the enrollee of inpatient coverage.

[4] We note that proposed 42 C.F.R. § 422.101(b)(2) contains a minor typographic error. The regulatory citation should read "42 CFR 412.622(a)(3)."

[5] OIG, Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care, p.14 (April 2022), *at* https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

[6] *Id.*

The FAH, however, is concerned that other revisions to 42 C.F.R. § 422.101(b)(2) could create confusion that undermines CMS' overarching goal of ensuring coverage of basic benefits for MA organization beneficiaries and perpetuates the inconsistent application of Medicare coverage criteria. In particular, the proposed amendment would eliminate the reference to "Medicare manuals and instructions" from 42 C.F.R. § 422.101(b)(2) and substitute a reference to "Traditional Medicare laws." ***Although the FAH agrees that the proposed reference to Traditional Medicare laws is appropriate and useful, the FAH is concerned that eliminating the reference to "manuals and instructions" could give the false impression that an MA organization can disregard the coverage criteria illustrated in these materials.*** In the April 2022 OIG report, the OIG cited a number of cases where the MA organization determined that the care did not meet Medicare coverage criteria, but OIG reviewers determined the care was in line with the Medicare Benefit Policy Manual (*e.g.,* Case IDs D236, D260, D426, D270, D278, D343, and D393, summarized in Appendix B of OIG's report). These reports demonstrate an existing problem of MA organizations disregarding or deviating from Medicare coverage criteria set forth in Medicare manuals and instructions, and the FAH is deeply concerned that removing express reference to manuals and instructions from 42 C.F.R. § 422.101(b)(2) could fuel these improper denials.

As the Supreme Court confirmed in *Azar v. Allina Health Services*, the Secretary is required to comply with the rulemaking requirements of 42 U.S.C. § 1395hh in establishing and changing substantive legal standards governing the scope of benefits and other matters, even when those standards might qualify as interpretive rules under the Administrative Procedure Act (APA). Nonetheless, the Medicare manuals and instructions continue to provide useful illustration and guidance regarding the general coverage and benefit conditions set forth in Medicare laws, and an MA organization should not be permitted to deviate from general coverage and benefit conditions as described in the manuals and instructions. Put simply, no Medicare beneficiary should be denied coverage for care that satisfies general coverage and benefit conditions included in Medicare manuals and instructions. The FAH therefore recommends that the proposed language be revised to broadly reference "Traditional Medicare laws, manuals, and instructions."

With respect to circumstances where an MA organization is subject to legal requirements that supersede Traditional Medicare laws, the FAH appreciates that this change appropriately avoids implying that a Part 422 regulation could supersede an applicable statute. The FAH, however, believes it would be more appropriate to reference specifically "laws applicable to <u>the</u> MA plan" in order to more precisely identify the scope of laws that might supplant a coverage condition in a particular context. In short, the existence of a superseding law applicable to one type of MA plan should not excuse another type of MA plan from adhering to the general coverage and benefit conditions included in Traditional Medicare laws.

Finally, although proposed 42 C.F.R. § 422.101(b)(2) does not expressly reference Medicare coverage criteria for inpatient care in other hospital settings (*e.g.*, inpatient psychiatric facilities and long-term care hospitals) and outpatient care in hospital outpatient departments and other settings, the FAH understands that MA organizations are required to apply Medicare coverage criteria for *all* basic benefits. We believe that it is clear from the regulatory texts that

the cited coverage criteria are provided as exemplars only, and we strongly support the inclusion of this non-exhaustive list of exemplar coverage criteria.[7]

With respect to the proposed regulatory text itself, the FAH urges CMS to finalize 42 C.F.R. § 422.101(b)(2) with revisions (1) to expressly reference manuals and instructions as explained above, (2) to correct the citation to IRF coverage criteria, and (3) to clarify that the second sentence provides examples of general coverage and benefit conditions. These recommended revisions read as follows:

> (2) General coverage and benefit conditions included in Traditional Medicare laws, **manuals, and instructions,** unless superseded by laws applicable to **the** MA ~~plans~~ **plan**. For example, **these general coverage and benefit conditions include** ~~this includes~~ coverage criteria for inpatient admissions at 42 CFR 412.3, requirements for coverage of Skilled Nursing Facility (SNF) Care and Home Health Services under 42 CFR part 409, and Inpatient Rehabilitation Facilities (IRF) coverage criteria at 42 CFR 412.622**(a)**(3).

Applicable Local Coverage Determinations (42 C.F.R. § 422.101(b)(3))

The FAH also appreciates CMS' discussion of the role local coverage determinations (LCDs) play in ensuring MA beneficiary coverage of basic benefits. We note, however, that MA organizations' current flexibility under 42 C.F.R. § 422.101(b)(3) to elect to apply coverage policies from other jurisdictions that the MA organization also serves if the policy is more favorable to its enrollees may not be sufficient to ensure that MA enrollees' coverage determinations are not less favorable than the Medicare coverage criteria that would apply under Traditional Medicare. CMS permits many hospitals that are part of "qualified chain providers" to enroll with the Medicare Administrative Contractor (MAC) with jurisdiction covering the geographic locale in which the chain provider's home office is physically located, pursuant to 42 C.F.R. § 421.404. In these situations, the LCDs that apply to the hospital may be different—and more favorable to the beneficiary—than those that apply to other hospitals in the community. ***This risk of less favorable coverage for MA beneficiaries could be effectively mitigated by a policy requiring MA plans to apply uniformly the coverage policy that is most beneficial to MA enrollees in all cases.*** Such a policy would be administratively less burdensome than determining which MAC has jurisdiction for particular providers' claims and would ensure that no MA beneficiary is subject to coverage criteria that are less beneficial than those applicable to Traditional Medicare beneficiaries receiving care from the same provider.

[7] In contrast, the FAH understands that certain Traditional Medicare rules—including in particular certification and recertification requirements set forth at 42 C.F.R. § 424.10 *et seq.*—establish conditions of payment that are not general coverage and benefit conditions. These certification and recertificaiton rules document the physician's medical necessity determination, which is unnecessary when an MA organization evaluates medical necessity as part of its UM activities. As such, proposed 42 C.F.R. § 422.101(b)(2) does not and should not incorporate certification and recertification rules.

Internal Coverage Criteria (Proposed 42 C.F.R. § 422.101(b)(6))

The FAH applauds CMS' proposal to include new language in 42 C.F.R. § 422.101(b)(6) to expressly limit the extent to which MA organizations may create internal coverage criteria and to require that any such criteria be based on "current evidence in widely used treatment guidelines or clinical literature that is made publicly available." In light of the clarification regarding the scope of established coverage criteria in proposed § 422.101(b)(2), the FAH believes that Traditional Medicare laws fully establish coverage criteria for many critical items and services that have been the subject of improper MA denials (particularly inpatient admissions to hospitals, IRFs, and other facilities). ***Thus, the explicit limitation in proposed § 422.101(b)(6) to situations where "coverage criteria are not fully established" effectively and appropriately limits MA plans' use of internal coverage criteria to those rare cases where Traditional Medicare laws do not establish coverage criteria for the item or service.*** Although the FAH believes that the proposed regulation makes this limitation on the use of internal coverage criteria clear, it may be appropriate to further clarify that internal coverage criteria may "*only*" be created when coverage criteria are not fully established under Traditional Medicare laws. In addition, it may be appropriate to mirror the language more closely to that used in subsections (b)(1) through (b)(3) by referencing Traditional Medicare laws, manuals, and instructions.

In those rare and limited circumstances where there is no Traditional Medicare coverage criterion at all for a particular benefit, transparency is critical to ensure that the MA organization's coverage criteria are fair and do not improperly hinder Medicare beneficiaries' ability to obtain benefits through the MA program. The FAH therefore strongly supports the proposal to require public disclosure by the MA organization of the particular sources of evidence on which its internal coverage criteria is based. These requirements are largely consistent with the statutory requirements applicable to LCDs under section 1862(*l*)(5)(D) of the Social Security Act (42 U.S.C. § 1395y(*l*)(5)(D)), and ***the FAH urges CMS to make further revisions to the proposed provision to further mirror the transparency requirements for LCDs and also to address particular transparency needs in the MA context.*** In particular, the public transparency requirements of proposed paragraph (b)(6) should be further revised as follows:

- ***45 Day Publicity Period*—**By statute, a new LCD cannot be made effective unless public availability requirements are satisfied for a 45-day period. The FAH believes that this minimal advance-disclosure period is critical to transparency for both providers and their patients enrolled in MA plans.

- ***Disclosure of Internal Coverage Policy***—It is the FAH's understanding that each internal coverage policy would be made publicly available under the Proposed Rule so that providers and enrollees alike would have adequate information regarding any internal coverage policies. Indeed, it would be difficult to evaluate whether the evidence summarized pursuant to proposed paragraph (b)(6)(i) provides an appropriate basis for the coverage criteria without a clear understanding of the criteria themselves. But the FAH urges CMS to make this requirement explicit in paragraph (b)(6) in order to avoid any ambiguity on this critical transparency protection.

- ***Absence of Traditional Medicare Coverage Criteria***—Similarly, an MA organization should be required to disclose the analytical process by which it determined that Traditional Medicare laws, manuals, instructions, NCDs, and LCDs fail to establish coverage criteria such that the MA organization is permitted to adopt internal coverage criteria at all with respect to a particular benefit. As noted above, the instances in which an MA organization would have this flexibility under the proposals set forth in the Proposed Rule are quite rare. In service of the goals of oversight and accountability, we urge CMS to expand proposed 42 C.F.R. § 422.101(b)(6) to require transparency by an MA organization on this front so that CMS, providers, and enrollees can evaluate whether the MA organization properly determined that coverage criteria are not fully established in Traditional Medicare laws, manuals, instructions, NCDs, and LCDs.

- ***Dates of Public Availability and Effective Date***—Finally, transparency around the MA organization's compliance with the public availability requirements and the effective dates of the internal coverage policy is important to avoid confusion among providers and enrollees and promote compliance. To that end, the MA organizations should disclose where and when it first made the internal coverage policy public and the policy's effective date.

In addition, even in those rare circumstances where an MA organization has the flexibility to develop and apply internal coverage criteria, the FAH urges CMS to clarify that those coverage criteria should not be so rigid as to not accommodate the exercise of professional judgment. In particular, the internal coverage criteria requirements should appropriately defer to the clinical judgment of the attending physician and the medical support for the physician's determination.[8]

In sum, the FAH recommends that CMS revise proposed 42 C.F.R. § 422.101(b)(6) to reflect the foregoing considerations such that the paragraph reads as follows:

> (6) ~~**When coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD,**~~ MA organizations may **only** create internal coverage criteria **policies applicable to a basic benefit in those rare circumstances when coverage criteria for the benefit are not fully established under Traditional Medicare laws, manuals, instructions, NCDs, or LCDs. Each internal coverage criterion must be** ~~**that are**~~ based on current evidence in widely used treatment guidelines or clinical literature**, incorporate appropriate**

[8] As discussed below in connection with reviews of medical necessity decisions (Part III.H), the FAH also urges CMS to require that the MA organization include peer-to-peer processes in their reviews of medical necessity decisions. Participation in a peer-to-peer discussion of a case should not be limited to the attending or ordering physician—other appropriate professionals, including but not limited to the physician on call for the attending physician or a member of the hospital's utilization review committee that has reviewed the case—are well positioned to engage on the case and provide information that may improve the accuracy of the resulting organization determination.

deference to the clinical judgment of the ordering physician, and be set forth in an internal coverage policy that satisfy the public availability requirements in this paragraph (b)(6) ~~**that is made publicly available**~~. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question. For internal coverage policies, the MA organization must **make the following information public on the MA organization's website at least 45 days before the effective date of such policy and for the duration of the policy** ~~**provide**~~:

(i) **Such internal coverage policy in its entirety;**

(ii) Each Medicare law, NCD, or LCD applicable to the item or service or a similar item or service and an explanation of the rationale supporting the MA organization's conclusion that such Traditional Medicare law(s), NCD(s), or LCD(s) do not establish coverage criteria for the item or service;

(iii) Where and when the internal coverage policy was first made public and the effective date;

(iv) A publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations;

(v)~~**(ii)**~~ A list of the sources of such evidence; and

(vi)~~**(iii)**~~ Include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination.

Finally, although the FAH supports limiting the development of internal coverage criteria to situations where their coverage criteria are not yet established in Traditional Medicare laws, LCDs, and NCDs, we do believe that MA plans should also have the flexibility to establish coverage criteria that are more beneficial than those set forth in LCDs. LCDs—unlike NCDs and Medicare statutes and regulations—are not binding on qualified independent contractors conducting reconsiderations pursuant to section 1869(c)(3)(B)(ii) of the Social Security Act (42 U.S.C. § 1395ff(c)(3)(B)(ii)). Likewise, an MA plan should have latitude to develop and apply internal coverage criteria that are more beneficial to enrollees than the otherwise-applicable LCD where there is no applicable NCD or Medicare statute or regulation. Such flexibility would enable MA organizations to appropriately respond to developing evidence that support broader coverage of an item or service notwithstanding the existence of a more limiting LCD that would not bind a qualified independent contractor making a reconsideration determination for a Traditional Medicare beneficiary.

Medical Necessity Determinations (Proposed Revisions to 42 C.F.R. § 422.101(c))

The FAH applauds CMS' proposal to revoke its 2000 policy and adopt "a narrower policy that permits MA organizations to continue to choose who provides Part A and Part B benefits through the creation of their contracted networks, but limits MA organizations' ability to limit when and how covered benefits are furnished when Traditional Medicare will cover different provider types or settings."[9] Limiting beneficiary access to covered services delivered by particular provider types or in certain settings misuses MA plans' utilization management functions to deprive or limit MA enrollees' access to certain basic benefits, contrary to the intent of the MA program. These practices create troubling inequities between Traditional Medicare and the MA program and unnecessary barriers to patients receiving care in the most clinically appropriate setting as determined by the professional judgment of their treating physician. As the OIG recently observed, "To reduce their costs, MA organizations may have an incentive to deny more expensive services, such as inpatient rehabilitation facility stays, and/or require that beneficiaries receive less expensive alternatives."[10] The proposed policy represents a key reform to temper MA organizations' ability to act on this incentive, and the FAH applauds CMS for working to address this issue.

The FAH also generally supports the proposal to describe the limited bases on which an MA organization can make a medical necessity determination in 42 C.F.R. § 422.101(c)(1), but urges CMS to clarify the regulatory text to read as follows:

> (1) *Medical necessity determinations.* (i) MA organizations must make medical necessity determinations ~~**based on**~~:
>
> > (A) **Based on coverage** ~~**Coverage**~~ and benefit criteria as specified at ~~**paragraphs**~~ **paragraph** (b) ~~**and (c)**~~ of this section and may not deny coverage for basic benefits based on coverage criteria not specified in paragraph (b) ~~**or (c)**~~ of this section;
> >
> > (B) **Based on whether** ~~**Whether**~~ the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act **in light of the**~~**; [¶] (C) The**~~ enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes; and
> >
> > ~~**(D)**~~ **(C) With the** ~~**Where appropriate,**~~ involvement of the organization's medical director **to the extent** ~~**as**~~ required **under** ~~**at**~~ § 422.562(a)(4).
>
> (ii) [Reserved]

[9] 87 Fed. Reg. at 79,502.

[10] *Id.*

With regard to proposed 42 C.F.R. § 422.101(c)(1)(i)(A), the FAH is concerned that the proposed language could create confusion and improper denials of basic benefits. In particular, this proposed provision references "coverage and benefit criteria as specified at paragraphs (b) *and (c)*" (emphasis added). The reference to paragraph (c) is circular and could be read to wrongly suggest that an MA organization has latitude to apply coverage criteria that are not specified in paragraph (b). The FAH understands that subsection (b) is designed to fully enumerate the sources of coverage criteria applicable to basic benefits and that an MA organization is not permitted to establish or implement internal coverage criterion other than in full compliance with the limitations and requirements of proposed paragraph (b)(6). ***Because the only coverage and benefit criteria for basic benefits are those set forth in subsection (b), the FAH urges CMS to strike the circular reference to paragraph (c) from proposed 42 C.F.R. § 422.101(c)(1)(i)(A).***

In addition, we recommend combining proposed clauses (B) and (C) to further clarify that the enrollee's medical history, physician recommendations, and clinical notes must inform the determination of whether the items or services are "reasonable and necessary" in proposed (c)(1)(B).

Lastly, the Proposed Rule solicits comments on when it would be appropriate for the MA organization's medical director to be involved in medical necessity determinations. The FAH believes that the scope of the medical director's involvement is properly governed by his or her responsibilities under § 422.562(a)(4) and recommends modifying proposed (1)(i)(D) to simply state that the medical director must be involved "to the extent required under § 422.562(a)(4)." As proposed, this subparagraph wrongly suggests that appropriateness is a separate consideration from the requirements of § 422.562(a)(4); rather, the extent of a medical director's involvement in medical necessity determinations should be governed by the medical director's obligation to ensure the clinical accuracy of all organization determinations and reconsiderations involving medical necessity.

III.E.3 Appropriate Use of Prior Authorization

We support CMS' proposal to promulgate a regulation explicitly setting forth MA program requirements with respect to prior authorization at 42 C.F.R. § 422.138 and endorse the express statement in the Proposed Rule that prior authorization "should not function to delay or discourage care."[11] Prior authorization is used widely by MA organizations to manage utilization, and when applied inconsistently or improperly, MA organizations' prior authorization practices threaten to compromise MA enrollees' access to care. In fact, FAH members report that it is not uncommon for prior authorization activities to delay or discourage care—including care that satisfies Traditional Medicare coverage criteria. Moreover, they report that they are unable to reply on prior authorization approvals because MA plans retrospectively deny coverage for previously authorized care. These practices operate to the detriment of MA enrollees and the MA program more generally, and the FAH appreciates CMS proposing express regulatory parameters for prior authorizations.

[11] 87 Fed. Reg. at 79,503.

As a preliminary matter, the FAH notes that prior authorization activities are not limited to outpatient or specialty care. Rather, they are widely used in situations including inpatient stays—including unscheduled inpatient admissions for post-stabilization care services (as defined in 42 C.F.R. § 422.113(c)(1)) and post-acute care (including IRF and long-term care hospital (LTCH) admissions). In some instances, prior authorization is required for each set increment of an enrollee's stay in a health facility. The Proposed Rule provides illustrations of the proposed prior authorization policies for acupuncture and non-emergency surgery, and although these illustrations are instructive, the FAH urges CMS to address the application of the prior authorization policies to post-stabilization and other unscheduled services that do not meet the definition of emergency, urgent, or stabilizing care. By way of example, in light of the proposed revisions to 42 C.F.R. § 422.101, it is the FAH's understanding that the prior authorization process for an inpatient hospital admission would focus on the coverage criteria set forth at 42 C.F.R. § 412.3 (*e.g.*, verifying the admitting physician's expectation that the patient will require hospital care that crosses two midnights).

Applicability to Concurrent Reviews. In the context of inpatient stays, MA organizations often authorize care through concurrent review processes because the review necessarily takes place when a patient is *already* receiving care from the provider. (This is particularly true when the MA organization requires authorization of post-stabilization services and/or when authorization is provided for defined periods with further authorizations over the course of the enrollee's stay, as discussed above.) In light of this practice, the FAH urges CMS to expand the scope of proposed 42 C.F.R. § 422.138 to include concurrent reviews in addition to prior authorizations. In particular, the guarantee of coverage described in paragraph (c) should apply regardless of whether the MA organization "approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage" *or* a determination of coverage made through concurrent review. In both cases, the MA organization furnishes its determination, and the provider furnishes services (or continues to furnish services) in reliance on that determination. It would be inappropriate and inequitable for an MA organization to call a review activity "concurrent review" and thereby escape the consequences of its authorization of care and representation of coverage through a semantic sleight of hand.

Effect of Authorization—Unanticipated Items and Services. The FAH also recommends that CMS revise 42 C.F.R. § 422.138 to provide that, where additional items and services are furnished in connection with the authorized item or service, the MA organization's coverage determination for those additional services cannot conflict with the prior authorization determination. In other words, the MA organization that approves the furnishing of an item or service through prior authorization based on the presence of a diagnosis or other medical criteria may not later deny coverage for the additional items and services by concluding that such diagnosis or medical criteria were not met. It is simply impossible for a provider to anticipate every single item or service that might be necessary for a particular patient in advance of treatment, and oftentimes, the full range of items and services necessary to care for a patient may only become evident midway through surgery, or at some point in the course of treatment. In those cases, it would be inappropriate and unduly risky for the additional items and services to be delayed pending further authorization by the MA organization. And it would be inappropriate for the MA organization to deny coverage for those unanticipated, additional items and services

in a manner that conflicts with its prior authorization of the anticipated items and services based on the presence of diagnoses and medical criteria.

Effect of Authorization—Coverage. The FAH fully supports the proposal in 42 C.F.R. § 422.138(c) to make clear that a pre-service determination of coverage precludes the MA organization from later denying coverage on the basis of the lack of medical necessity. Too often, FAH members report the retrospective denial of coverage for care that the MA organization approved through a prior authorization, rendering the prior authorization meaningless, and the FAH appreciates CMS seeking to address this problem with express regulatory text confirming that prior authorizations are binding with respect to coverage.[12] The FAH, however, recommends that the words "or payment" be stricken from proposed 42 C.F.R. § 422.138(c) as the prior authorization regulation should focus exclusively on coverage. A determination of coverage certainly creates an obligation on the part of the MA organization to make payment once care is delivered and a claim is submitted, but the determination of coverage and payment are analytically distinct concepts that should not be confused. In the alternative, if the words are not stricken, the beginning of the second phrase should be revised to adopt a parallel structure as follows: "it may not deny coverage <u>or payment</u> later . . ." except in the specified circumstances.

Effect of Authorization—Good Cause, Fraud, or Similar Fault. The FAH is concerned that the proposed regulation will not effectively ensure coverage for authorized services because the proposed "good cause" standard and cross-referenced reopening rules are too flexible and would inappropriately shift risk from the MA organization to the provider. Rather, the MA organization should only be permitted to deny coverage despite a prior authorization on the basis of fraud or similar fault on the part of the provider. The prior authorization process is designed to provide a pre-service assurance of coverage in the normal course, but if an MA organization is permitted to reverse a prior authorization determination after the services have been furnished and in the absence of provider fraud or misrepresentation, the prior authorization becomes hollow and puts the provider at risk for any MA organization reevaluation of the determination based on newly available information or other developments. Instead, in light of the prospective nature of prior authorization determinations, the MA organizations' latitude to later deny coverage of authorized items or services should be limited to circumstances involving material fraud or misrepresentation by the provider. Therefore, we urge CMS to revise the exception in proposed 42 C.F.R. § 422.138(c) to strike the reference to "good cause" and the flexible reopening provisions at 42 C.F.R. § 422.616, as follows: "unless the prior authorization was procured by provider fraud or misrepresentation."

Prior Authorization Processes and Timing. The FAH notes that CMS has separately proposed a rule entitled "Advancing Interoperability and Improving Prior Authorization Processes" for MA plans and other specified payers (the "Prior Authorization Proposed Rule").[13] The Prior Authorization Proposed Rule includes, *inter alia*, revisions to the requirements for MA

[12] As discussed above, however, the FAH urges CMS to make this language expressly applicable to authorizations furnished by way of concurrent reviews in addition to prior authorizations and pre-service determinations of coverage.

[13] 87 Fed. Reg. 76,238 (Dec. 13, 2022).

prior authorization decision timeframes and communications. The FAH will therefore respond more fully on the aspects of MA plan prior authorization that are the subject of that proposed rule in separate comments to that proposed rule but notes here that the existing and proposed timeframes for MA organization determinations are excessive and result in inappropriate delays in needed care. It is the FAH's view that expedited prior authorization determinations should be made promptly—within a couple hours—and other prior authorization determinations should be made within 72 hours. The long timeframes under current law and the Prior Authorization Proposed Rule permit excessive waits for prior authorization determinations, creating uncertainty for MA enrollees and the providers that treat them and delaying discharges to post-acute care.

III.E.5 Mandated Annual Review of Utilization Management (UM) Policies by a UM Committee (42 C.F.R. § 422.137)

The FAH strongly support CMS' proposal to require MA organizations to establish a utilization management (UM) committee that is led by the MA plan's medical director and is responsible for formally adopting each of the MA plan's UM policies and procedures. This proposal will assure greater transparency, consistency, and regulatory compliance across UM policies and procedures, including prior authorization policies and procedures. As discussed in comments on Parts III.E.5.c and III.H, below, the FAH supports expanding the UM committee requirements to expressly specify that the UM committee must (1) investigate and adopt corrective actions to address the causes of manual review errors and system errors; (2) adopt, review, and revise policies and procedures regarding the appropriate expertise of reviewing physicians and health care professionals, and (3) document the justifying rationales for the selection criteria for the MA organizations' reviewers. In addition, the FAH offers a few additional suggestions in this section to ensure that the establishment of these UM committees serves CMS' broader goal of ensuring all Medicare beneficiaries enjoy access to and coverage for the full scope of Medicare benefits.

Compliance Deadline. The FAH strongly supports the proposed January 1, 2024 deadline for an MA organization to constitute the UM committee and properly review and approve the necessary UM policies and procedures. We agree that the time between the issuance of a final rule and the start of the contract year (typically six months or more) will provide MA organizations with sufficient time to "engage in the necessary administrative activity to establish the UM committee and have its existing UM policies reviewed."[14] Indeed, the proposed requirements for UM committees represent common-sense standards for the adoption of rules that govern beneficiary access to care, and the application of UM policies and procedures that have not undergone the proposed review and approval process would pose significant risks to beneficiary coverage rights as well as program integrity that far exceed the operational burdens of the proposed effective date. In short, if an MA organization cannot adopt policies in a manner that satisfies these requirements by the end of this calendar year, those policies simply should not be applied to Medicare beneficiaries unless and until they can be properly reviewed and adopted by the UM committee.

[14] 87 Fed. Reg. at 79,505.

UM Committee Responsibilities. The FAH broadly supports proposed 42 C.F.R. § 422.137(d), which would require the UM Committee to review, approve, and revise UM policies and procedures in accordance with regulatory requirements; clearly articulate and document processes to demonstrate that the review, approval, and revisions requirements are met; and document in writing the reason for its decisions regarding the development of UM policies and make that documentation available to CMS upon request. The FAH, however, favors targeted revisions to the UM committee responsibilities in order to promote meaningful review, foster appropriate provider engagement, ensure appropriate oversight of UM practices, and clarify that internal coverage policies fall squarely within the scope of UM policies and procedures within the UM committee's jurisdiction.

First, although the FAH appreciates the proposal to require the UM committee to review UM policies and procedures "at least annually" in proposed 42 C.F.R. § 422.137(d)(1), we are concerned that focus on an annual review process may lead to "rubber stamping" of such policies without meaningful review and substantive engagement by the UM committee. ***Rather, we urge CMS to require that these reviews be undertaken "as necessary, and at least annually."*** For example, if a new Medicare regulation is promulgated setting out or refining coverage criteria on August 2nd, it would be improper for a UM committee to wait for its annual review of the applicable UM committee and determine whether revisions are necessary. Instead, the UM committee should be engaged in ongoing reviews of UM policies and procedures so that appropriate revisions can be adopted and implemented in a timely manner. In addition, revising proposed (d)(1) to reference reviews "as necessary, and at least annually" would better support the requirement in proposed (d)(3) (revise UM policies and procedures "as necessary").

Second, in furtherance of robust and appropriate provider engagement, the FAH urges CMS to require each MA organization's UM committee to ***ensure that the UM policies and procedures are developed in consultation with contracted providers and are communicated to providers and (when appropriate) enrollees***. Both requirements would foster the type of transparency and engagement that has historically enhanced the development and implementation of MA policies. The proposed regulation appropriately cross-references the standards at 42 C.F.R. § 422.202(b)(1), but the FAH supports separately cross-referencing the provider consultation requirement at 42 C.F.R. § 422.202(b), the communication requirement at 42 C.F.R. § 422.202(b)(2), and the consistency requirement at 42 C.F.R. § 422.202(b)(3).

Third, the FAH supports expanding the duties of the UM committee to ***include all internal coverage policies of the MA plan***. It makes little difference whether a policy is explicitly called "utilization management" or a "coverage criteria"—rather, the relevant question should be whether the policy or procedure may be applied to limit enrollee access to plan-covered services. Moreover, the UM committee is best positioned to ensure that any internal coverage policies fully comply with the requirements of proposed 42 C.F.R. § 422.101(b)(6). For example, the UM committee should be responsible for verifying that it is permissible to adopt internal coverage criteria for an item or service (*e.g.*, confirming that Medicare coverage criteria have not been established for the item or service). The UM committee should also be responsible for monitoring and evaluating developments in Medicare coverage criteria on an ongoing basis to determine when the MA plan's internal coverage criteria can no longer be applied.

UM Committee Composition. The FAH supports further revisions to and refinements of the UM committee composition requirements at 42 C.F.R. § 422.137(c)(1) through (4) in order to ensure that the UM committee has the requisite expertise to fulfill its obligations. First, the majority of UM committee members should be experts regarding the care of elderly or disabled individuals because the UM committee's obligations focus on establishing UM policies and procedures that will apply to MA enrollees, who by virtue of Medicare's eligibility criteria, are elderly or disabled individuals. Expertise with this population should therefore be nearly universal among the practicing physicians that serve on the UM committee. In addition, the FAH appreciates CMS' acknowledgement of feedback that UM policies are often not reviewed by providers with expertise appropriate for that service. The FAH strongly supports revising the UM committee regulation to require that a UM committee member with expertise in the use or medical need for a specific item or service should be required to participate in the UM committee's review of a UM policy applicable to that item or service. Thus, for example, a UM committee review of an IRF UM policy should be conducted with the participation of a committee member that is a medical rehabilitation physician with IRF experience, and a UM committee review of a partial hospitalization program (PHP) UM policy should be conducted with the participation of a committee member that is a psychiatrist with PHP expertise.

Delegated Entities. Finally, we urge CMS to clarify that, while UM activities may be delegated (subject to specific limitations set forth in 42 C.F.R. § 422.504(i), as discussed in greater detail in our comments regarding delegation below), the establishment and operation of a UM committee is a core MA organization function that *cannot* be delegated. This committee is charged with ensuring the MA organization's adherence to the fundamental responsibility to provide Medicare beneficiaries with basic benefits in accordance with Medicare coverage criteria, and this activity is inappropriate for delegation to a third party. Moreover, the UM committee should be expressly charged with an ongoing and active oversight role in ensuring that decisions made by an MA plan—and its delegated entities—are consistent with the final approved practice guidelines and UM policies.

III.E.6.a Termination of Services in Post-Acute Care

Utilization review activities, in addition to being inherently burdensome for providers, may be particularly problematic in the context of post-acute care because MA organizations' reviewers often lack the post-acute training and qualifications to properly assess the medical necessity of inpatient rehabilitation and other post-acute care. As a result, post-acute providers are burdened with inappropriate denials and appeals that can interrupt patient timely access to needed rehabilitation services in the most medically appropriate setting.

With respect to MA organizations' practice of authorizing treatment in discrete increments, the FAH's members have reported that this practice is commonplace, particularly with respect to SNFs and IRFs. In order to ensure that such services are covered in an equitable manner, the FAH supports revisions to proposed 42 C.F.R. § 422.138 to make this language (including the coverage requirements of subsection (c)) applicable to concurrent reviews, including those that continue or deny authorization for subsequent discrete increments. (*See* discussion of Part III.E.3, *supra*.)

The FAH also appreciates CMS' solicitation of comments regarding complaints that MA organizations prematurely terminate beneficiaries' coverage of post-acute care before the beneficiaries are healthy enough to return home and the potential impact of the certain proposed regulatory amendments on these practices. It is particularly concerning that some terminations come on the heels of a quality improvement organization (QIO) decision reauthorizing coverage. It is the FAH's view that proposed 42 C.F.R. § 422.101(b) ought to be applied to prevent such premature terminations of coverage because the coverage criteria are fully developed under Traditional Medicare laws and the MA organization should not be permitted to apply more limiting internal coverage criteria. As explained further below, however, robust oversight and enforcement will be critical to maximizing the benefit of these regulatory changes and refinements.

III.E.6.c Manual Review Errors and System Errors

As explained in the April 2022 OIG report and summarized in the Proposed Rule, improper MA plan denials are too often the result of MA plan errors, both human and system related. These errors have significant costs for enrollees—who may delay or forego needed care and experience unnecessary uncertainty regarding their coverage—and their providers who incur the transactional costs of appeals. ***Based on OIG documentation of these issues and reports from members, it is the FAH's belief that the existing incentives for MA plans to identify and reduce manual review errors and system errors at the MA plan level and among all delegated entities are simply insufficient to prompt MA organizations to undertake adequate investigations and corrective actions to reduce the risk of future errors.***

The FAH wholly endorses CMS' view that the OIG's April 2022 report clearly "identified this area as a compliance risk that MA organizations *must address* in accordance with § 422.503(b)(4)(vi)(F) and (G)."[15] In short, the prevalence of manual review errors and system errors without corrective action to prevent such errors reflects the failure to comply with obligations *under existing law*. ***The FAH therefore urges CMS to support robust enforcement of these requirements.*** As part of this effort, it may be appropriate to further revise 42 C.F.R. § 422.503(b)(4)(vi) to expressly address these obligations, including the obligation to collect data on these errors, investigate the causes of errors, and take corrective action to reduce inappropriate denials.

The FAH also appreciates CMS' solicitation of comments on whether and how proposed 42 C.F.R. § 422.137 could be revised to help reduce the vulnerabilities that can lead to manual review errors and system errors. The FAH strongly supports revising 42 C.F.R. § 422.137(d) to require the UM Committee to review data on manual review errors, system errors, and excessive denials, to revise UM policies and procedures as appropriate to reduce the risk of such errors, and to identify and implement system changes to mitigate the risk of manual review errors and system errors.

[15] 87 Fed. Reg. at 79,508 (emphasis added).

III.E Other Topics Relevant to Utilization Management

Delegation. The FAH strongly supports CMS' UM proposals, subject to our comments above, but we are concerned that MA organizations' frequent use of third-party entities to handle UM activities might undermine CMS' efforts to rein in the abuses targeted by the Proposed Rule. We urge CMS to clarify that, like any other activity that is the responsibility of an MA organization, an MA organization can only delegate UM activities in a manner consistent with the requirements set forth in 42 C.F.R. § 422.504(i) and, importantly, the MA organization "maintains ultimately responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS." To this end, the FAH understands that existing MA regulations require the MA organization to monitor the performance of the delegated entity on an ongoing basis and require that the delegated entity comply with all applicable Medicare laws, regulations, manuals, and instructions.

Downcoding and Charge Audits. We also want to observe that MA organizations continue to engage in the routine practice of "downcoding" and aggressive coding and charge audits, which the FAH has addressed in previous comment letters. Downcoding describes the all-too-widespread practice of recoding billed services (*e.g.*, reducing the level of care or changing a diagnosis code), while charge audits target the removal of covered charges or the bundling of covered charges for separately payable services. Both downcoding and charge audits are often undertaken by third-party private contractors retained by MA organizations on a contingency fee basis and conducted by staff with minimal clinical or billing expertise. Downcoding and charge audits do not provide an adequate explanation for the denial or downgraded DRG or other code, and often create confusion due to lack of communication between MA plans and their third-party contractors. These issues are exacerbated due to convoluted and nearly insurmountable appeal processes, as discussed further below. CMS acted several years ago to curb these types of unfair practices under the Medicare fee-for-service recovery audit contractor (RAC) program and should exercise similar oversight of these practices under the MA program.

It is the FAH's belief that MA plan audits that downcode provider claims or remove charges in the absence of provider fraud or misrepresentation improperly deny enrollee coverage without regard for the MA plan's obligation to provide coverage in accordance with Medicare coverage criteria and medical necessity determinations. In other words, as long as the provider's claim accurately reports the patient's diagnoses and care furnished (*i.e.*, does not misrepresent the facts), once the MA plan determines medical necessity, the MA plan should be prohibited from changing codes or removing charges as doing so effectively denies coverage to the enrollee for that care. Although the FAH believes that this is the natural consequence of the UM and coverage requirements, we also urge CMS to clarify that downcoding is impermissible absent legitimate program integrity concerns such as fraud or misrepresentation by the provider.

Oversight and Enforcement. Finally, and most importantly, ***the FAH strongly encourages CMS to undertake robust oversight and enforcement activities, including audits, to ensure that MA UM activities comply with these requirements so that MA enrollee are properly provided full coverage for Medicare covered items and services.*** OIG recommends in its April 2022 report that CMS "update its audit protocols to look for issues identified in this

report." We urge CMS to adopt this recommendation, and to establish a process by which providers and beneficiaries alike can report instances of noncompliance to CMS to inform those audits. In order for these audits to be most effective, the FAH also recommends that CMS expand the basis for sanctions outlined in 42 C.F.R. § 422.752 to expressly include failures on the part of the MA organization to comply with the UM requirements that will be established or amended by this rule when finalized.

In addition, providers and beneficiaries should have a mechanism to escalate denials as well as violations of MA organizations' own UM policies to CMS for resolution through CMS. The FAH is concerned that the dispute resolution processes built into providers' agreements with MA organizations are better suited to payment issues, not coverage issues that directly affect beneficiaries and should be resolved with CMS' involvement. Moreover, the MA organizations' appeals processes are complex, cumbersome, not standard across plans, often not automated, and require significant administrative resources and staffing for health care providers. As a practical matter, these dispute resolution processes are often prohibitively time- and resource-intensive. At a minimum, the FAH urges CMS to robustly respond to provider complaints regarding MA organizations' failure to comply with the full range of CMS UM regulations and coverage requirements.

III.H Review of Medical Necessity Decisions by Appropriate Professionals (§§ 422.566 & 422.629)

The FAH supports CMS' efforts to address provider associations' feedback regarding the expertise of the physicians and health care professions that review organization determinations. As the FAH has previously described, members report that MAO utilization review activities (including prior authorization, concurrent review, or retrospective review) are too frequently conducted by individuals or contractors who lack specific training or credentials in key specialties. These problems can be particularly severe where the medical necessity of IRF care or behavioral health services are under review because many MA organizations do not generally have sufficient rehabilitation physicians and behavioral health professionals reviewing medical necessity determinations.

Although the FAH is supportive of CMS' goals in amending the regulations applicable to organization determinations, including authorizations and concurrent reviews, the FAH is concerned that the problems highlighted by provider associations will not be addressed insofar as the proposed amendments borrow language currently applicable to plan reconsiderations and members report similar problems with respect to plan reconsiderations. Along these lines, the emphasis on "plan flexibility and operational efficiency" in the Proposed Rule[16] could be misinterpreted as providing broad discretion to select reviewers that in fact lack the requisite expertise.

To address this issue, ***the FAH urges CMS to further specify, for example, that the health professional evaluating a request regarding admission to an IRF be a rehabilitation physician with IRF experience and that the health professional evaluating a request regarding***

[16] 87 Fed. Reg. at 79,510.

admission to an inpatient psychiatric facility (IPF) be a psychiatrist with IPF experience. It is the FAH's understanding that this is the intent of the Proposed Rule based on the examples set forth therein, but further clarification with these or similar examples would provide appropriate guidance on the limits of plan flexibility while focusing on two key areas where providers report that reviewer expertise is often lacking.

In addition, the FAH urges CMS to further revise the proposed UM Committee regulation to establish the UM Committee's responsibilities with respect to the selection of physicians and other health care professionals conducting medical necessity reviews. In particular, ***the UM Committee should be required to adopt, review, and revise policies and procedures regarding the appropriate expertise of reviewing physicians and health care professionals and also document the justifying rationales for the selection criteria for the MA organizations' reviewers.*** This approach would promote transparency and accountability with respect to the selection of appropriately qualified reviewers.

Finally, addressing the problem of improper denials also necessitates appropriate engagement between the MA organizations' medical reviewer and an appropriate professional with sufficient knowledge of the case. Where MA organizations appropriately engage their medical reviewers with treating professionals in a peer-to-peer process, this approach can increase the accuracy of organization determinations and reduce appeals. Therefore, ***the FAH urges CMS to consider requiring MA organizations to engage in a peer-to-peer process with the treating professional or another professional with sufficient knowledge of the case.*** This peer-to-peer process should not be limited to the admitting or attending physician, who may not be readily available at the time of the organization determination. Rather, the MA organization's peer-to-peer process should be flexible enough to accommodate the participation of other professionals with sufficient knowledge of the case (*e.g.*, a physician on call for the attending physician or a member of the hospital's utilization review committee that has reviewed the case).

III.A Health Equity in Medicare Advantage (§§ 422.111, 422.112, and 422.152)

The FAH applauds CMS' commitment to implementing Executive Order 13985 by way of important changes to the MA program. Our members are well versed in disparities in access to care faced by MA enrollees. Barriers to care exist for MA enrollees who belong to the communities identified in the Proposed Rule – including people with limited English proficiency or reading skills; ethnic, cultural, racial or religious minorities; people with disabilities; people with diverse sexual orientations or gender identities; and people living in rural areas or facing poverty or inequality. ***We therefore strongly support CMS' proposal to expand the scope of 42 C.F.R. § 422.112(a)(8) to encompass the wide range of populations for whom MA organizations must make a concerted effort to ensure equitable access to care.*** We also note that many of the structural features that distinguish MA from Traditional Medicare, including the use of narrow networks and various utilization controls, oftentimes pose more significant barriers to precisely these populations. We therefore urge CMS to engage in targeted oversight and data collection to ensure that these populations do not face disproportionately long wait times or frequent denials of care.

In addition, the FAH supports CMS' proposal to amend 42 C.F.R. § 422.111(b)(3)(i) to improve provider directories by incorporating information about providers' cultural and linguistic capabilities, as well as identifying MOUD-waivered providers. We agree that periodic online provider directory reviews by CMS are necessary to oversee compliance with these requirements, which serve the goal of health equity by helping enrollees access the providers most appropriate for their needs.

III.B Behavioral Health in Medicare Advantage (§§ 422.112, 422.113, and 422.116)

The FAH supports the Administration's commitment to behavioral health and the specific proposals set forth in the Proposed Rule to enhance MA enrollees' access to behavioral health services. As highlighted in the preamble text, these efforts often dovetail with the overarching goal of enhancing health equity, particularly with respect to areas suffering from shortages of mental health professionals.

Network Adequacy and Continuity of Care. The FAH strongly supports CMS' proposals relating to MA behavioral health network adequacy and continuity of care. In particular, we urge CMS to finalize the following proposals:

- Adding clinical psychology, clinical social work, and Prescribers of Medication for Opioid Use Disorder to the list at 42 C.F.R. § 422.116(b)(1) along with the associated access and network adequacy standards (*i.e.*, time, distance, and minimum ratios) for each of these three new specialty types.
- Amending the access standards at 42 C.F.R. § 422.112(a)(1)(i) to specify that the network must also include providers that specialize in behavioral health services.
- Adding behavioral health services to the types of services for which MA organizations must have programs in place to ensure continuity of care and integration of services at 42 C.F.R. § 422.112(b)(3).

Emergency Medical Conditions. The FAH enthusiastically supports CMS' proposal to add language that will "definitively clarify that an emergency medical condition can be physical or mental in nature,"[17] but requests that CMS considers adopting regulatory language that more closely mirrors the language found in the recent surprise billing regulations at 45 C.F.R. § 149.110(c)(1). In particular, the FAH recommends that CMS replace "a medical condition, mental or physical," in proposed 42 C.F.R. § 422.113(b)(1)(i) with "a medical condition, including a mental health condition or substance use disorder." Expressly referencing substance use disorders in this way would more fully confirm the scope of emergency medical conditions and avoid the risk that an MA organization might view the difference in language between the two provisions as suggesting a material difference in the scope of emergency medical conditions covered by the regulations.

Wait Time Standards. The FAH also supports CMS' proposal to codify appointment wait times as standards for primary care services that are the same as the appointment wait times described in the Manual and to extend those standards to behavioral health services, as well as a requirement for applicants for new and existing service areas to attest to compliance with these

[17] 87 Fed. Reg. at 79,491.

requirements. We would support the adoption of the standards applicable to qualified health plans in the Federally-Facilitated Exchange, though we would discourage CMS from giving MA organizations the leeway to achieve those standards only 95% of the time. Rather, we feel that health equity would be undermined by allowing an MA organization to fail to ensure access for any portion of its enrollees, particularly because those enrollees who are likely to face long wait times for behavioral health services may be those with the most pressing need.

III.C Medicare Advantage Network Adequacy: Access to Services (§ 422.112)

The FAH supports CMS' attention to network adequacy and its proposals to strengthen beneficiary access to care in the MA program. ***In particular, we strongly support the proposal to amend 42 C.F.R. § 422.112 to clarify that an MA organization must arrange for any medically necessary covered benefit (including both specialty and non-specialty care) outside of the plan provider network at in-network cost sharing when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs.*** The language at proposed 42 C.F.R. § 422.112(a)(1)(iii) appropriately codifies CMS' interpretation of the relevant statutory and regulatory requirements as reflected in the Manual and avoids any confusion that might result from current language applying this standard with only respect to specialty care.

Timely Access to Post-Acute Providers. The FAH also supports further refinements to 42 C.F.R. § 422.112(a)(1)(iii) and to the network adequacy requirements at 42 C.F.R. § 422.116(e)(2)(iii) to particularly address the problem of MA plans failing to maintain an adequate network of post-acute providers. MA plans' networks are often thin on post-acute providers, which creates challenges for hospitals seeking a medically appropriate destination that is willing and able to accept a timely patient transfer. At present, the minimum number requirement under 42 C.F.R. § 422.116(e)(2)(iii) can be satisfied with a single in-network skilled nursing facility (SNF), creating little incentive for MA plans to develop robust post-acute networks. We urge CMS to establish minimum network adequacy requirements for LTCHs and IRFs, in addition to SNFs, in recognition of the fact that these providers serve distinct, critical roles under the umbrella of post-acute care. FAH members report that the dearth of in-network post-acute providers results in inappropriately prolonged inpatient hospital stays for MA enrollees in need of post-acute care, delaying and disrupting the enrollee's transition to medically necessary post-acute care (including care at LTCHs, IRFs, and SNFs). In addition, this practice has adverse impacts on acute care capacity as acute care beds are deployed for MA enrollees in need of post-acute care. The absence of robust network adequacy requirements for post-acute providers is further compounded by the financial incentives for MA plans. Because a delayed discharge to post-acute care often reduces payment to the post-acute provider without increasing the hospital's per-discharge payment amount, MA plans have neither a regulatory nor a financial incentive to remedy gaps in their post-acute networks.

The FAH, therefore, urges CMS to clarify that in-network post-acute care is unavailable or inadequate to meet an enrollees' needs under 42 C.F.R. § 422.112(a)(1)(iii) when such care has been ordered and satisfies coverage criteria but is not immediately available. In such a case, the enrollee should be permitted to access out-of-network post-acute care at in-network cost sharing and/or the MA plan should be required to provide additional payment to the hospital in

the amount that would have been paid to the post-acute provider for that day of care. These approaches would provide an appropriate counterbalance to the MA plan's existing incentives and refocus efforts around ensuring the enrollee's access to timely and appropriate care. In addition, the FAH urges CMS to scrutinize MA plans' networks for inclusion of post-acute care providers by raising the minimum number requirement for post-acute facilities and monitoring enrollee wait times for discharge to these facilities.

Sub-Networks. The FAH also supports the adoption of network adequacy requirements specific to each sub-network used by an MA organization in order to ensure that covered benefits remain available and accessible to each enrollee in the service area. MA organization "sub-networks"—downstream organizations that provide administrative and health care services to beneficiaries—are often affiliated with their own contracted or employed physician or provider groups. MAOs' 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, rendering network access to those providers illusory. Moreover, 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.

The FAH recommends that CMS evaluate networks at the level at which beneficiaries actually have access to care, taking into account the MA organization's sub-network structures. We further recommend CMS take action to foster MA organization network transparency to protect MA beneficiary's access to care by implementing audit protocols to identify and review the adequacy of these downstream organizations' provider networks and taking appropriate network enforcement actions for noncompliance with network adequacy standards.

Transparency Around Network Quality. In order to generally support transparency around network adequacy issues, CMS should include a standard in the Star Ratings Program that highlights both the adequacy and the stability of an MA plan's network. Specifically, CMS should design a measure to ensure that beneficiaries are aware of the historical problems that any MA plan has had both with the initial adequacy of its networks and with the changes an MA plan has made during the course of a plan year that affect its networks. In addition, to further ensure CMS' review of an MA plan's network meaningfully evaluates beneficiary access to care, we urge CMS to establish additional requirements focused on MAOs' use of "sub-networks" and the sufficiency of their post-acute provider networks.

Summary of Recommendations. The FAH recommends five actions to address the foregoing concerns with respect to sub-networks and post-acute network adequacy. First, CMS should implement audit protocols that identify and review network adequacy at the sub-network level and take enforcement action, as necessary, for noncompliance with network adequacy standards. Second, CMS should require that MA plans demonstrate meaningful enrollee access

to post-acute providers, including by requiring a sufficient ratio of in-network IRF and LTCH to enrollees. SNFs, IRFs, and LTCHs are fundamentally distinct providers. SNFs alone do not adequately reflect the full spectrum of available "rehabilitation" that is available/accessible in a MAO's market. Third, CMS should audit MA plan practices associated with effectuating timely discharges to an appropriate post-acute care setting and consider a corresponding quality measure for timely discharge in Star Ratings. Fourth, when the MA plan cannot arrange for *timely* in-network post-acute care, the MA enrollee should be entitled to out-of-network post-acute care at in-network cost sharing and/or the hospital should receive an additional payment in the amount that would have been paid to the post-acute provider for each excess day of hospital care. Lastly, CMS should include a standard in the Star Ratings Program to promote the adequacy and stability of an MA plan's network, as discussed above.

III.D Enrollee Notification Requirements for MA Provider Contract Terminations (§§ 422.111 and 422.2267)

The FAH appreciates CMS revisiting the enrollee notification requirements for MA provider contract terminations that were established more than two decades ago. Mid-year contract terminations can be disruptive to MA enrollees that may have carefully evaluated their MA plans provider network when choosing their coverage. As such, the FAH supports robust engagement with enrollees prior to the effective date of a contract termination, but urges CMS to make some revisions to its proposed amendments to 42 C.F.R. § 422.111(e).

For Cause and Without Cause Terminations. The FAH agrees with CMS that, in most cases, the notice period for a contract termination is sufficient to enable the MA organization to notify enrollees 30 days in advance of a contract termination such that the flexibility of a "good faith effort" standard is unnecessary for most notifications. But the FAH is concerned that the Proposed Rule's approach of distinguishing between not-for-cause and for-cause terminations and only eliminating the good faith effort standard for not-for-cause terminations creates an inappropriate incentive to characterize a termination as for-cause regardless of the timing of the termination. Rather, the FAH urges CMS to require that the MA organization provide enrollees notice of a termination of a contracted provider within the timeframes required by paragraph (e) when the MA organization makes the decision to terminate the provider or receives the provider's notice terminating the contract 60 days or more before the date of contract termination and to make a good faith effort to comply with the timeframes in all other circumstances. Where an MA organization is aware of a pending termination 60 days or more in advance, the MA organization should be able to provide enrollees with 45- or 30-days' advance notice, as applicable, regardless of whether the termination is for cause or without cause.

Notification to Enrollees Who Have Ever Been Patients of a Hospital. The FAH strongly supports the proposed enhanced notification requirements for contract terminations that involve a primary care or behavioral health provider, but urges CMS to consider applying one aspect of that proposal to hospitals and other health facilities. ***In particular, the FAH recommends extending the requirement of proposed 42 C.F.R. § 422.111(e)(1)(iii) to health facilities such that, for a termination involving a hospital or other health facility, the MA organization would be required to provide notice to all enrollees who have ever been patients of that hospital or health facility.*** The current standard only requires that notice be provided to

enrollees who are assigned to, currently receiving care from, or have received care within the past three months from a provider or facility being terminated. These enrollees, however, only represent a small fraction of the MA enrollees that look to and depend on a particular facility for care. Under this standard, for example, an MA enrollee that has consistently sought and received care at a particular hospital (other than an inpatient psychiatric facility) would not receive notice if the enrollee did not receive care at the hospital within the preceding three months. This limitation creates a lack of transparency around facility terminations, leaving enrollees in the dark about critical changes to their MA plan's provider network, and the FAH urges CMS to instead require notification to all enrollees who have ever been patients of the facility being terminated.

Notice Requirements for Primary Care and Behavioral Health Terminations. The FAH strongly supports the proposed new provisions regarding enrollee notice requirements for contract terminations that involve a primary care or behavioral health provider. The FAH agrees with CMS' assessment that contract terminations involving primary care or behavioral health providers and facilities warrant more intensive enrollee notification requirements, including both written and telephonic notice at least 45 calendar days before the termination effective date. As such, proposed 42 C.F.R. § 422.111(e)(1) should be finalized as proposed.

Enrollment Options. Under proposed 42 C.F.R. § 422.2267(e)(12)(ii)(D), the Provider Termination Notice would be required to provide enrollees information about the annual coordinated election period and the MA open enrollment period and to provide information about requesting assistance in identifying and switching to other coverage or requesting consideration for a special election period (SEP). The FAH supports these proposed additions to the Provider Termination Notice, but requests that CMS establish explicit standards for when termination of a provider from the network should serve as a basis for SEP eligibility. The FAH supports clarifying that any enrollee that has ever received care from a particular provider or facility is eligible for a SEP upon termination of that provider or facility, as is an enrollee that attests to confirming the provider's or facility's network participation when choosing an MA plan. Changes to an MA plan's network configuration can be extraordinarily destabilizing to MA enrollees that considered their provider preferences when selecting a plan, and an SEP would allow the enrollee to reevaluate that choice of plan based on network changes.

III.P Medicare Advantage and Part D Marketing

Discussion of Beneficiary Needs Prior to Enrollment. The FAH is dismayed by the results of CMS' review of marketing and enrollment audio calls, which reflect a failure to gather adequate information about the beneficiary's needs and goals in over 80 percent of cases, and strongly agrees with CMS that a beneficiary cannot be enrolled in a plan that best meets his or her needs when an agent or broker "fails to ask the beneficiary about their current providers, including specialists and preferred hospitals or other facilities."[18] The FAH therefore urges CMS to finalize proposed 42 C.F.R. § 422.2274(c)(12) with a revision to expressly address the beneficiary's preferred hospital as a required topic regarding beneficiary needs in a health plan choice. The FAH also agrees with CMS that the beneficiary's preferred hospital is a pertinent

[18] 87 Fed. Reg. at 79,534.

question in marketing and enrollment calls, and therefore urges CMS to expressly include preferred hospitals as a required topic. With this revision, proposed 42 C.F.R. § 422.2274(c)(12) would read as follows:

> Ensure that, prior to an enrollment, CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics include information regarding primary care providers**,** ~~**and**~~ specialists**, and facilities** (that is, whether or not the beneficiary's current providers **and preferred hospitals or other facilities** are in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), costs of health care services, premiums, benefits, and specific health care needs.

Transparency Regarding MA Organizations' UM Practices. The FAH believes that MA enrollees are entitled to critical transparency around MA organizations records with respect to UM activities, denials, overturns, Star Ratings, and network adequacy and stability. In the Prior Authorization Proposed Rule, CMS proposes requiring MA organizations and others to publicly report specified prior authorization metrics. The FAH will provide separate comments addressing proposed 42 C.F.R. § 422.122(c) in response to the Prior Authorization Proposed Rule, but the FAH urges CMS to also consider further revisions to 42 C.F.R. §§ 422.2265(c) and 422.2267(e)(4), respectively, to require MA organizations to post prior authorization metrics on the MA organization's website and to include it in the pre-enrollment checklist or other marketing materials. In addition, the FAH supports adding Star Rating measures focused on UM activities and network adequacy and stability so that Medicare beneficiaries will have more meaningful information regarding their choices of MA plans.

III.W Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 422.326(c), 423.360(c), (§ 401.305(a)(2))

The FAH broadly supports CMS' proposal to abandon the "reasonable diligence" standard for overpayments under 42 C.F.R. § 401.305(a)(2) with a False Claims Act standard of "knowing" and "knowingly." As noted in the Proposed Rule, the overpayment provisions of the Affordable Care Act use the False Claims Act definition of the terms "knowing" and "knowingly."[19] The regulations promulgated to implement this rule for purposes of Medicare Part A and Part B (42 C.F.R. §§ 401.301 *et seq*.) and for purposes of Medicare Part C and Part D (42 C.F.R. §§ 422.326, 423.360), however, "impermissibly created False Claims Act liability for mere negligence"[20] by adopting a "reasonable diligence" standard. The FAH applauds CMS' acquiescence to the court's ruling and confirmation that a violation of the overpayment statute requires knowing conduct (*i.e.*, actual knowledge, deliberate ignorance, or reckless disregard).

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[19] Social Security Act § 1128J(d)(4)(A), 42 U.S.C. § 1320a-7k(d)(4) (citing 31 U.S.C. § 3729(b)).

[20] 87 Fed. Reg. at 79,559 (citing *care Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 191 (D.D.C. 2018), rev'd in part on other grounds sub nom. *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), cert. denied, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21-1140)).

Nonetheless, the FAH is concerned that, if finalized as proposed, the amended regulation would create unnecessary confusion as to the continued applicability of the extraordinarily pragmatic and useful "quantification" element in the identification of overpayments. Therefore, the FAH urges CMS to consider revising proposed 42 C.F.R. § 401.305(a)(2) to read as follows:[21]

> A person has identified an overpayment when the person knowingly receives or retains ~~an~~ **a quantified** overpayment. The term 'knowingly' has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

Alternatively, this sentence could be revised to specify that a person "has identified an overpayment when the person knowingly receives or retains an overpayment **and quantifies the amount of the overpayment**."

As originally proposed, 42 C.F.R. § 401.305(a)(2) would have provided that "[a] person has identified an overpayment if the person has actual knowledge of the existence of an overpayment or acts in reckless disregard or deliberate ignorance of the overpayment."[22] Commenters, however, "questioned how quantification of the overpayment fit into the Proposed Rule," emphasizing "the difference between determining that an overpayment has been received and the auditing work necessary to calculate the overpayment amount."[23] In response, CMS "agree[d]" and "revised the language in § 401.305(a)(2) to clarify that part of identification is quantifying the amount."[24] Thus, a provider or supplier could have full knowledge of the existence of an overpayment, but the 60-day report and return period would not begin until the overpayment was also quantified (or, using the reasonable diligence standard, should have been quantified). In the Final Rule, CMS went on to explain that the quantification element avoids the necessity of piecemeal report and returns as individual overpayments on specific claims are uncovered. Rather, the preamble to the Final Rule confirmed that a "provider or supplier should not report and return overpayments on specific claims from the probe sample until the full overpayment is identified," which might involve quantification of the full amount of the overpayment through direct calculation or statistical sampling and extrapolation.[25]

Despite CMS' current and unchallenged policy making quantification an element of the identification of an overpayment and the supporting rationale for this policy, the proposed amendment to 42 C.F.R. § 401.305(a)(2) would eliminate reference to quantification. Because the Proposed Rule does not discuss eliminating of the quantification element, the FAH does not

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[21] The FAH likewise supports parallel revisions to 42 C.F.R. §§ 422.326(c) and 423.360(c), but focuses herein on the Part A and Part B overpayment rules.

[22] Medicare Program; Reporting and Returning of Overpayments, 77 Fed. Reg. 9,179, 9,187 (Feb. 16, 2012).

[23] Medicare Program; Reporting and Returning of Overpayments, in Medicare Parts A and B, 81 Fed. Reg. 7654, 7,661 (Feb. 12, 2016) (hereinafter the Final Rule).

[24] *Id.*

[25] *Id.* at 7,664.

believe that CMS is proposing to modify this element of its overpayment policy, which has been in place for seven years.[26] Nonetheless, the FAH is concerned that the proposed amendment could be misread to suggest that quantification is no longer a component of identification. At a minimum, the absence of such language in the Final Rule would fuel uncertainty as providers and suppliers seek to comply in good faith with an ambiguous rule.

The FAH therefore urges CMS to revise the proposed amendment to include a reference to the critical step of quantification as part of the identification of an overpayment. As noted above, this could be achieved by simply modifying "an overpayment" to reference "a quantified overpayment." Alternatively, this sentence could be revised to specify that a person identifies an overpayment when the person "knowingly receives or retains an overpayment and quantifies the amount of the overpayment." Either approach would appropriately confirm that a provider not acting in reckless disregard or deliberate ignorance of the existence or quantification of an overpayment will be in compliance with the provider's report and return obligations provided that the provider reports and returns such overpayment within 60 days of quantifying the amount of an overpayment (whether through direct calculation or extrapolation).

V. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

The FAH appreciates CMS' attention to MA organizations' UM practices in this Proposed Rule and believes that beneficiaries should have access to meaningful information regarding MA organizations' coverage denial practices to inform their choice of MA plan. We thus continue to urge CMS to consider refinements to its MA organization oversight by developing new quality metrics for MA organization operations for future inclusion in the Star Ratings Program. New quality measures should be developed to rate and report on patient access problems related to appeals and denial overturn rates for prior authorization, appeals and overturn rates for payment denials, network adequacy, and service delays. As we shared in our letter dated May 19, 2022, the FAH is currently developing a new MA quality measure concept on Level 1 Appeals to highlight overturn rates for health plans. This measure would supplement the current measure evaluating Level 2 Appeals. We believe such measures would promote competition on these critical access-oriented dimensions of MA plan quality, rewarding and incentivizing better MAO behavior and providing Medicare beneficiaries with critical information on the potential for excessive plan denials for service. We hope to share more on this work with you and your staff soon.

[26] If this is incorrect, the FAH notes the absence of any supporting rationale for such a change in the Proposed Rule, thus foreclosing meaningful public comment.

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Thank you for the opportunity to comment on the Proposed Rule. If you have any questions, please contact me or a member of my staff at 202-624-1534.

Sincerely,