April 3, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: Prior Authorization under Medicare Advantage and the Patients over Paperwork initiative

Dear Administrator Verma:

On behalf of the Regulatory Relief Coalition, we thank you and your staff for your efforts in reducing barriers to patient access through your Patients over Paperwork initiative. This Administration's commitment to review and eliminate unnecessary regulations and burdens has given physicians hope of being able to spend more time with patients.

We are following up on one of the top administrative burdens under Medicare -- Medicare Advantage Organizations' (MAOs') prior authorization requirements. We strongly believe that CMS guidance and oversight in this area is timely and necessary to reduce some of the unnecessary administrative burden of these requirements and to maintain beneficiary access to needed health services.

We very much appreciate the Administration's responsiveness to these concerns. In December, we met with your Principal Deputy, Demetrios Kouzoukas, to discuss the legal requirements applicable to MAOs' prior authorization processes[1] and sent him legal analyses which (1) focus on statutory limits on prior authorization and the need to ensure that prior authorization processes do not impose inappropriate barriers to access; and (2) address additional issues, including legal requirements related to time limits, notices and appeals, HIPAA administrative simplification, and statutory transparency requirements.

In part as the result of that meeting, the *2019* ***Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies and 2019 Call Letter*** (2019 Call Letter) includes a provision that addresses the transparency and timeliness of MAO prior authorization processes as well as language precluding prior authorization for participation in Medicare-qualified clinical trials. We believe that the inclusion of these provisions in the 2019 Draft Call Letter lays the groundwork for a comprehensive approach to this issue and we look forward to working with CMS to ensure that the requirements set forth in the 2019 Call Letter are enforced through MAO reporting requirements and CMS' MA plan audit procedures.

[1] See Attachment A

Following the issuance of the 2019 Draft Call Letter and as a follow up to our meeting with Mr. Kouzoukas, we met with a number of CMS officials in Baltimore to discuss what additional CMS action should be taken to alleviate the administrative burdens posed by MAOs' prior authorization requirements. One of the goals of the Patients Over Paperwork initiative is to "increase the proportion of tasks that CMS customers can do in a completely digital way." For that reason, we recommend CMS adopt the NCPDP SCRIPT Standard Version 2013101 Prior Authorization transactions in order to encourage adoption of technology that allows for real time prior authorizations.

Furthermore, we have asked CMS to issue guidance to MAOs regarding their use of prior authorization to ensure that all statutory and regulatory requirements are met and that prior authorization does not create inappropriate barriers to access for Medicare patients[2]. Second, we have also requested that CMS increase its scrutiny of MAO processes and procedures, during the MAO audit process. We look forward to following up with CMS staff on these requests.

Meanwhile, we continue to be aware of cases of actual patient harm which demonstrate the urgency of this effort. For example, we are aware that, in one case, due to delays caused by pre-authorization requirements imposed by an Arizona MAO that impacted a Medicare patient's narcolepsy medication, the patient had two falls, two hospitalizations, and a hip fracture while waiting for PA. Prior authorization is routinely required for services, such as transplantation, cancer, and treatment of blinding eye disease, that are extremely unlikely to be performed if they are not medically necessary.

We look forward to working with you and others at CMS to build on the action that CMS has already taken to help address the burden of prior authorization under Medicare Advantage.

Sincerely yours,

American Academy of Dermatology Association
American Academy of Neurology
American Academy of Ophthalmology
American Association of Neurological Surgeons/
Congress of Neurological Surgeons
American College of Rheumatology
American Society of Clinical Oncology
American Urological Association

[2] To help facilitate this process, we have prepared draft guidance from CMS to MAOs outlining criteria that should be met for prior authorization processes to meet statutory and regulatory requirements. (See Attachment B) Notably, associations representing private plans, including the Association of Health Insurance Plans (AHIP) and Blue Cross/Blue Shield Association (BC/BS) themselves recognized the need to streamline and simplify prior authorization processes by adopting the **Consensus Statement on Improving the Prior Authorization Process** https://www.mgma.com/getattachment/Government-Affairs/Issues-overview/Health-Information-Technology/Administrative-Simplification/Administrative-Simplification/Finalized-PA-consensus-statement-120717-logos.pdf) . The guidelines document we have submitted for consideration by CMS staff reflects the principles in the managed care industry's own Consensus Statement.

Attachment A

POWERS

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ATTORNEYS AT LAW

MEMORANDUM

To: Regulatory Relief Coalition
From Diane Millman
Peggy Tighe
Re: Use of Prior Authorization (PA) by Medicare Advantage Organizations (MAOs): Legal Analysis
Date: October 19, 2017

This responds to your request for a legal analysis of whether MAOs are legally authorized to impose PA restrictions on the coverage of Part B items and services that function primarily as a barrier to access. This memo also provides a summary of the regulatory requirements applicable to MAOs' PA processes.

Findings:

As set forth in the analysis below, it appears that the extensive use of PA for services that are not explicitly subject to PA under Medicare Fee-for-Service is legally problematic to the extent that such procedures erect barriers to the provision of medically necessary services. Additional clarification is needed from CMS regarding the circumstances under which a MAO may impose PA requirements without creating barriers to access that are inconsistent with the Medicare statute and regulations. In addition, PA decisions are "organization determinations," which are subject to specific beneficiary notification, clinical review, and appeal requirements as well as transparency requirements and uniform format requirements that do not appear to be strictly enforced at this time.

Background

You have raised concerns that MAOs routinely and increasingly use PA processes as means to deter physicians from ordering or providing medically necessary services for MA enrollees, rather than as a legitimate mechanism for identifying medically unnecessary services. MAOs generally approve most services for which PA is required, strongly suggesting that these procedures are of dubious cost effectiveness as mechanisms for identifying and precluding the provision of medically unnecessary services. A review of MAO websites also suggests that MAOs frequently limit coverage by imposing PA requirements on services whose coverage is supposed to be determined based on local or national coverage determinations (which MAOs are required to apply) and for procedures (such as cancer treatment and transplantation) that are not likely to be subject to overutilization. However, because the administrative burdens for providers and beneficiaries are considerable and are thought to deter physicians from ordering or providing services, PA requirements are proliferating.

CMS historically has refrained from exercising significant oversight over MAOs' use of PA, and the CMS officials with whom we have discussed the issue appear to view PA as largely a matter of contractual negotiations between the MAO plan and providers and thus outside of CMS' purview. However, this view begs the question of whether, and to what extent, extensive use of PA with the purpose and effect of dissuading physicians from ordering medically necessary services is legal under the Medicare Act and regulations, and this is the question that you have requested us to address.

A. PA is legally problematic when used primarily as a barrier to access for medically necessary Part A and Part B items and services.

Medicare beneficiaries, regardless of whether they are receiving care through the Medicare fee-for-service (FFS) system or through a MAO, retain the right to access medically necessary Medicare Part B covered items and services. The Medicare statute expressly requires that MAOs "provide to members enrolled under [Medicare Advantage] . . . benefits under the original Medicare fee-for-service program option," defining these benefits as "those items and services (other than hospice care) for which benefits are available under parts A and B."[3] Medicare regulations and transmittals likewise reflect this requirement for equal coverage.[4] Under "Original" FFS Medicare, mandatory PA is authorized by statute only for certain durable medical equipment and certain other non-physician services, which appears to suggest that its application to physicians' services and other Medicare Part A and Part B items and services is legally problematic.

Accordingly, CMS has taken the position that certain types of pre-service coverage restrictions may, in fact, violate the governing statute and regulations. For example, the agency's September 2012 memorandum to, Section 1876 Cost Contractors, Section 1833 Health Care Prepayment Plans and PACE Organizations (the "September 2012 Memo"), indicates that plans are not permitted to impose "step therapy" limitations on coverage of certain Part B drugs or services, unless also required through Original Medicare. The memorandum specifically states that coverage policies "may not be more restrictive than what Original Medicare allows and may not impose barriers to Parts A and B services." (Emphasis added).

Based on our preliminary review of some of the PA requirements imposed by MAOs, it appears that a very good case could be made that a number of these requirements, like step therapy coverage limits, are "more restrictive than what Original Medicare allows" and "impose barriers to Part A and B services." For example, the PA criteria for some services require the Medicare beneficiary to wait for a specified period before a diagnostic or therapeutic service will be approved or to require one type of treatment to be tried before another is approved—regardless of the patient's particular medical condition or individual need. Such restrictions appear to be quite comparable to the step therapy limits disapproved by the September 12 Memorandum. Yet, the same restrictions on the use of step therapy that were set forth in the September 2012 Memorandum have never been applied to PA determinations.

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[3] Social Security Act (SSA) § 1852(a)(1)(A),(B) (emphasis added).

[4] See 42 C.F.R. § 422.100(a) (MA plans "must provide enrollees with coverage of the basic [Original Medicare] benefits described in paragraph (c) of this section (and, to the extent applicable, the [supplemental] benefits described in § 422.102) by furnishing the benefits directly or through arrangements, or by paying for the benefits"); 42 C.F.R. § 422.101(a) and (b) (MA plans must "[p]rovide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare" and must comply with CMS National Coverage Determinations, coverage guidelines in Original Medicare manuals, and Local Coverage Determinations of Medicare contractors with jurisdiction in the MA plans' geographic area (subject to a special rule on MA plans that cover geographic areas encompassing multiple local coverage policy areas.

The imposition of mandatory PA for physicians' services, in particular, is particularly problematic. In 2003, Congress implicitly rejected mandatory PA for Part B physicians' services by enacting Section 1869(h) of the Social Security Act, which authorized a voluntary "prior determination" process for physicians' services, but specifically provided that neither a negative "prior determination" nor a decision to refrain from seeking a "prior determination" may impact the beneficiary's right to obtain the services, seek reimbursement, and then appeal any adverse coverage determination..[5] By contrast, failure to abide by a MAO's PA process results in automatic denial of the service at issue, regardless of medical necessity. Since coverage under MA and Medicare Fee-for-Service are required to be comparable, Congress' enactment of Section 1869(h) suggests that the application of such mandatory PA restrictions on coverage of physicians' services is legally problematic.

A. **The Legal Requirements Applicable to PA Processes and Determinations**

You have also requested us to specify the legal requirements that must be met for PA processes and determinations for those items and services that may be legally subject to PA.

1. PA Determinations are subject to regulatory time limits, beneficiary notification and other requirements which have not been the focus of regulatory oversight.

It is clear that, if a MAO requires a service to be approved before it is performed in order for the service to be covered, a negative PA determination is an "organization determination"[6] within the meaning of the Medicare regulations. Organization determinations are subject to specified requirements that are set forth in the Medicare regulations. For example, the regulations (at 42 CFR §422.566(d)) states that:

> If the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession. . .

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[5] SSA, §1869(h) (6)(B). The implementing regulations, issued in 2008,[5] noted that this "prior determination" process for physicians' services was "an optional process" that "[did] not preclude either the beneficiary or the provider from obtaining or performing the service and submitting the claim for payment." 73 Fed. Reg. 9672, 9675 (Feb. 22, 2008)

[6] Specifically, Medicare regulations (42 CFR §422.566(b)(3)-(5) defines a MAO "organization determination" to include, among other things,

> (3) The MA organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization.
> (4) Reduction, or premature discontinuation, of a previously authorized ongoing course of treatment
> (5) Failure of the MA organization to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee.

In addition, the Medicare Act provides that:

> A reconsideration relating to a determination to deny coverage based on a lack of medical necessity shall be made only by a physician with appropriate expertise in the field of medicine which necessitates treatment who is other than a physician involved in the initial determination.

SSA §1852(g)(2)(B). This provision applies to requests for reconsideration of the denial of a PA request.

Likewise, "organization determinations" are subject to specific beneficiary notice, appeal and other requirements, as set forth in 42 CFR §422.560 et seq. (e.g. 14-day time limit for a "standard" organization determination and 72 hours for an "expedited" decision). However, it is unclear to us whether or not MAOs are in compliance with these time limits, and it does not appear that CMS has focused on the application of these time limits in the context of PA. In addition, the current regulations governing "organization determinations" do not state that a positive PA decision is binding on the MAO, and we understand from you that, in fact, MAOs have denied coverage for services that obtained prior approval.

2. MAO PA Forms are required to be standardized based on HIPAA requirements.

The CMS regulations applicable to MAOs (42 CFR §422.504(h)(2)) specifically require MAOs to comply with HIPAA simplification regulations. The HIPAA regulations require that all health plans (including but not limited to MAOs) use a particular IT standard format (the 278 Standard) [7] for all PA electronic transactions[8] effective on and after January 1, 2012. [9] In part because CMS has failed to finalize a standard for the submission of supporting medical documentation (the Attachment Standard), many health plans are not making the 278 Standard available to providers, as required by applicable regulations. Moreover, health plans that wish to circumvent the 278 Standard can take advantage of a regulatory exception for "direct data entry transactions" and establish their own proprietary website processes for PA requests. While these websites are not required to use the 278 Standard, they are required to use the applicable data content and data condition requirements of the 278 Standard.[10]

3. Transparency Requirements

Section 1852(c)(1)(G) of the Social Security Act specifically requires that each MAO disclose, in clear, accurate, and standardized form to each enrollee:

> Rules regarding prior authorization or other review requirements that could result in nonpayment.

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[7] Formally, the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 - Health Care Services Review - Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review- - Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1.

[8] In HIPAA parlance, "referral certification and authorization" transactions

[9] 45 CFR §162.1302.

[10] 45 CFR § 162.923(b) ("Exception for direct data entry transactions.")

Such disclosure must be made at the time of enrollment and at least annually thereafter. It is unclear to us whether and to what extent MAOs have complied with these rules as PA requirements have proliferated.

Attachment B

DATE: [To be supplied]
TO: Medicare Advantage Organizations
FROM: [To be supplied]
SUBJECT: Guidance on Imposing Prior Authorization Requirements on Part A and Part B Items and Services

The purpose of this memorandum is to provide guidance to Medicare Advantage Organizations (MAOs), regarding the implementation of prior authorization requirements for Medicare Part A and Part B items and services, and the circumstances under which prior authorization may be determined to constitute a barrier to access.

The Social Security Act and implementing regulations[11] require MAOs to provide all benefits covered under Original Medicare, with certain limited exceptions. In general, this means that MAOs must provide, at a minimum, equal access to items and services covered by Original Medicare in their service area. As stated in Section 110.1.1 of the Medicare Managed Care Manual, while MAOs may utilize prior authorization, plans may not implement prior authorization protocols "that create inappropriate barriers to needed care."

Items and Services Subject to Prior Authorization

Because prior authorization constitutes a pre-service limitation on coverage, it has the potential to inhibit the provision of medically necessary care in a manner that (with certain very limited exceptions) is not permitted under original Medicare. For that reason, MAOs are urged to use prior authorization sparingly and never should be required for emergency care.

As a general principal, the use of prior authorization should be limited to those items and services for which there is clear evidence of overutilization (i.e. documented utilization patterns over time or among similarly situated provider suggest overuse) and for which case by case review is practicable (i.e. there are clear clinical criteria for identifying medically unnecessary services based on a patient's medical records or other individually identifiable clinical data). MAOs are encouraged to review their lists of items and services currently subject to prior authorization and to eliminate prior authorization requirements for categories of services that are rarely denied on the grounds of medical necessity. Prior authorization lists should be re-reviewed annually to ensure that items and services on the list continue to meet these criteria. MAOs should maintain documentation of evidence of overutilization of the services on their PA lists and of annual reviews.

In addition, generalized prior authorization requirements should not be imposed if there are less onerous means to ensure that items and services ordered or provided are medically necessary. For example, the development and dissemination of a coverage policy based on established clinical guidelines and on input from participating providers may address the identified

[11] 42 C.F.R. § 422.101(a)

overutilization, especially if accompanied by focused educational efforts and if compliance is framed as an alternative to prior authorization. MAOs also may consider requiring providers to submit documentation of medical necessity along with claims for payment for services that are identified as potentially overused, or using post-payment audits to review medical necessity.

When a MAO decides that prior authorization is necessary, consideration should be given to applying the prior authorization process as narrowly as possible, to "outlier" providers whose ordering or prescribing patterns differ significantly from their peers after adjusting for patient financial risk from prior authorization requirements.

Additionally, MA plans are bound by local and national coverage determinations (LCDs and NCDs) and for that reason, any prior authorization requirements imposed for items and services that are subject to a LCD or NCD should be limited to determining whether the conditions set forth in the LCD or NCD have been met.

Prior Approval Criteria

Prior authorization should be based on current and accurate clinical criteria. MAOs are reminded that Medicare beneficiaries are entitled to coverage of medically necessary Part A and B services and that cost alone is not a basis for denying approval. The criteria used to determine whether or not prior authorization is granted should be readily available to providers and the public, along with citations to relevant clinical literature or professional guidelines.

MAOs are reminded that prior authorization by its nature is intended to take into account the beneficiary's individual medical condition and circumstances. Therefore, prior authorization criteria should not include inflexible requirements for coverage or categorical exclusions that impose stringent coverage rules without accommodation of exceptions. For example, MAOs should refrain from imposing step therapy requirements, blanket requirements for a beneficiary to engage in one course or therapy before initiating another, and requirements that a beneficiary re-engage in a failed treatment regimen.

Whenever possible, prior authorization criteria should facilitate the one-time approval of a course of therapy in order to avoid interruptions in care, and should be sufficiently broad to enable providers to accommodate a patient's response to treatment and new clinical information without the need for additional approval. Likewise, MAOs are urged to formulate prior authorization criteria in a manner that enables providers to provide services within the same CPT family without seeking additional approval.

Processing Prior Authorization Requests

MAOs are cautioned that prior authorization processes that are administratively cumbersome have the potential to create inappropriate barriers to needed care. For this reason, MAOs should seek to ensure that the processes used for providers to obtain prior authorization –whether administered directly or through a contract with a third party — are as streamlined as practicable.

To ensure that the paperwork process alone does not erect inappropriate barriers to access, providers should be notified in advance of all medical documentation that may be needed to process the request and the documentation required to be submitted should be minimized to the extent practicable. The mechanism for submission of medical records or other documentation should be designed to comply with federal and state privacy laws and the MAO should establish processes to ensure that sensitive medical documentation is mot mislaid or mishandled. MAO quality assurance processes should be used to identify, document, and correct deficiencies in processing prior authorization requests. MAOs remain responsible for exercising oversight over prior authorization processes administered by third parties to ensure that these requirements are met.

Along similar lines, CMS regulations (42 CFR §422.504(h)(2)) specifically require MAOs to comply with HIPAA simplification regulations. The HIPAA regulations (45 CFR §162.1302) require that all health plans (including but not limited to MAOs) give providers the option to file prior authorization requests (i.e. HIPAA "referral certification and authorization" transactions) using electronic transmission and further require the use of a specified transaction standard.[12] Any health plan that utilizes its own proprietary website processes for prior authorization requests are required to ensure that such processes meet the same data content and data condition requirements as the transaction standard.

Prior Authorization Deadlines, Notices and Appeals

MAOs are reminded that prior authorization determinations constitute "organization determinations" that are subject to the provider and beneficiary notices, appeals, and timelines set forth in the regulations. While the regulations (42 CFR §422.560 et seq.) impose a 14-day time limit for a "standard" organization determination and 72 hours for an "expedited" decision, these deadlines were established with post-payment review in mind. In order to assure continuity of care, it is recommended that MAOs abide by more circumscribed deadlines in making pre-service determinations (e.g. within 48 hours of obtaining all necessary information for standard organization determinations and within 24 hours of obtaining all necessary information, for expedited determinations.)

Eligibility and all other medical policy coverage determinations should be performed as part of the prior authorization process, and a prior authorization approval should be treated as a binding coverage determination. Providers and beneficiaries should be timely notified of all prior authorization determinations and applicable appeal rights.

In addition, MAOs are reminded that the Medicare regulations include specific requirements regarding the qualifications of those who make "organization determinations" (including prior authorization denials). Specifically, the regulations (at 42 CFR §422.566(d)) state that, upon

[12] Formally, the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 - Health Care Services Review - Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review- - Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1.

initial review, a partial or full denial must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria. In addition, §1852(g)(2)(B) of the Social Security Act requires reconsideration requests to be addressed by physicians with appropriate expertise in the field of medicine involved and who meet other regulatory requirements.

Transparency

Section 1852(c)(1)(G) of the Medicare Act specifically requires that each MAO disclose, in clear, accurate, and standardized form to each enrollee, "Rules regarding prior authorization or other review requirements that could result in nonpayment." Such disclosure must be made at the time of enrollment and at least annually thereafter.

MAOs should disclose prior authorization requirements, including electronic links to the items and services requiring prior authorization, in any beneficiary enrollment information. All prior authorization information should be accurate and current, including applicable effective dates, and the list of services subject to prior authorization should not be modified during the period covered by the enrollment. If prior authorization is required for referrals outside of network providers such requirements should be clearly disclosed to beneficiaries at the time of enrollment.

CMS Oversight

CMS plans to review MAO use of prior authorization for Medicare Part A and Part B services as part of its oversight responsibility over the coming year. In conducting this activity, CMS plans to review MAO lists of items and services subject to prior authorization to ensure that they meet the criteria set forth in this memorandum and to ensure that lists are not so extensive that, taken as a whole, the prior approval program imposes an inappropriate barrier to access.

In addition, CMS will review MAO prior authorization processes (whether conducted directly or under third party contract) to ensure that they are operated in a streamlined and efficient manner that complies with applicable HIPAA administrative simplification requirements. Provider and beneficiary notices and appeal processes will be examined to ensure that regulatory requirements applicable to "organization determinations" are met, and beneficiary enrollment and related materials will be reviewed to ensure that rules regarding prior authorization and other review requirements that could result in nonpayment are disclosed in clear, accurate, and standardized form.