

May 24, 2018

Centers for Medicare & Medicaid
Services
[Document Identifiers: CMS–10249 and
CMS–10261]
Agency Information Collection
Activities: Proposed Collection;
Comment Request

Dear Sir or Madam:

On behalf of the Regulatory Relief Coalition, including the undersigned professional associations, we are pleased to have the opportunity to comment on the Paperwork Reduction Act notice published in the *Federal Register* on March 26, 2018. See 83 *Federal Register* No. 58 (March 26, 2018) (the “MAO Reporting Requirement Notice” or the “Notice”). This Notice solicits comments on the information that Medicare Advantage Organizations (MAOs) will be required to report to CMS in 2019 in the form entitled, “Part C Medicare Advantage Reporting Requirements.”

As indicated in the Notice, MAOs are required to have an effective procedure to report to CMS statistics and other information with respect to (among other things) patterns of service utilization and the availability, accessibility and acceptability of its services. In the Notice, CMS proposes to add 18 new data elements to the reporting requirements applicable to Organization Determinations and Reconsiderations (ODR). We support the inclusion of the proposed new data elements to provide CMS with additional information regarding the circumstances under which ODRs are made. In addition, we believe that it is critical to add a number of additional new data fields to collect information relating to MAOs’ use of Organization Determinations that are made pursuant to Prior Authorization (PA) processes and procedures.

The 2019 Medicare Advantage Call Letter explicitly states that requests for PA are requests for organization determinations. Therefore, all MAO determinations on these requests are organization determinations that are (or should be) subject to reporting to CMS. The extensive use of PA by MAOs and other health plans places an extraordinary administrative burden on physicians; in fact, Relief from the extraordinarily burdensome PA requirements is the single most important regulatory relief priority for physicians. And, as set forth in a letter sent by the Regulatory Relief Coalition to CMS Administrator Seema Verma,¹ indiscriminate imposition on of PA requirements is inconsistent with 1) the Administration’s Patients before Paperwork initiative and 2) longstanding Medicare policy, that precludes MAOs from creating inappropriate barriers to access. In fact, 45 patient organizations have expressed concern over MAOs’ use of PA and requested additional CMS oversight.² In addition, a number of associations representing health plans have themselves recognized the problem and urged health plans to exercise restraint in the use of PA.³

To improve oversight over the use (and misuse) of PA by MAOs, it is critical for CMS to collect additional information regarding the PA requirements imposed by MAOs and the Organization

¹ Attachment A.

² Attachment B.

³ See <https://www.ama-assn.org/sites/default/files/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>.

Determinations made pursuant to PA processes (e.g. whether the service is approved, partially approved, denied, or partially denied). At this time, it does not appear that MAOs routinely report to CMS all PA determinations as “organization determinations”; nor do MAOs report the number and nature of the services subject to PA or the number of requests for PA for each service; the disposition of PA requests. Without this information, we do not believe that CMS is in a position to exercise the increased oversight requested by the patient and provider communities.

Accordingly, we request that the ODR section of the data reporting for entitled “Part C Medicare Advantage Reporting Requirements” be modified as follows:

Request: We request that the ODR section of the form entitled “Medicare Part C Reporting Requirements be modified to:

- ***Make it clear that each request for PA is a request for an organization determination;***
- ***Require all MAOs to report the following information for each procedure subject to PA:***
 - ***The specific service or procedure involved;***
 - ***The number of requests for PA received for the procedure;***
 - ***The number of requests for PA for the service or procedure that were approved in full, approved in part, denied in full and denied in part.***
 - ***The number of denials appealed;***
 - ***The number of denials reversed on appeal and the number of denials affirmed on appeal;***
- ***Require all PA data elements be reported separately from other organization determination data and facilitates data aggregation.***

CMS should ensure that this data is made available to the public.

We strongly believe that requiring MAOs to report this data in a uniform and consistent manner is a necessary first step to ensuring appropriate access for Medicare beneficiaries who choose to enroll in a MA plan and will facilitate the oversight requested by patient and provider groups.

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 Cardiology
American College of Rheumatology
American College of Surgeons
American Society of Clinical Oncology
American Urological Association

Attachment A

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 processes⁴ 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.

⁴ 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 patients⁵. 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

⁵ 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 B: Patient Organizations expressing concern about MAO use of PA, in letters sent to CMS Administrator Seema Verma:

- ALS Association
- American Macular Degeneration Foundation
- Arthritis Foundation
- Academy of Spinal Cord Injury Professionals (ASCIP)
- American Association of People with Disabilities (AAPD)
- American Academy of Physical Medicine and Rehabilitation (AAPM&R)
- American Association on Health and Disability
- American Occupational Therapy Association (AOTA)
- American Physical Therapy Association (APTA)
- American Spinal Injury Association (ASIA)
- American Therapeutic Recreation Association (ATRA)
- Association of Academic Physiatrists (AAP)
- Association of University Centers on Disabilities (AUCD)
- Brain Injury Association of America (BIAA)
- Center for Medicare Advocacy
- Christopher & Dana Reeve Foundation
- Epilepsy Foundation
- Falling Forward Foundation
- National Multiple Sclerosis Society (NMSS)
- Lakeshore Foundation
- National Association of State Head Injury Administrators
- Paralyzed Veterans of America (PVA)
- United Spinal Association
- Association for Pelvic Organ Prolapse
- Brain Injury Association of America
- Cystitis Association
- Kidney Cancer Action Network
- Lupus and Allied Diseases Association
- Lupus Foundation of America
- Multiple Sclerosis Association of America
- MS Focus
- Oxalosis & Hyperoxaluria Foundation
- Prevent Blindness
- Schizophrenia And Related Disorders Alliance of America
- Scleroderma Foundation
- The Simon Foundation for Continence
- Sjögren's Syndrome Foundation

- The Tourette Association of America
- Triage Cancer
- Underactive Bladder Foundation
- United Spinal Association
- Us TOO International Prostate Cancer Education & Support
- Veterans Health Council



Consensus Statement on Improving the Prior Authorization Process

Our organizations represent health care providers (physicians, pharmacists, medical groups, and hospitals) and health plans. We have partnered to identify opportunities to improve the prior authorization process, with the goals of promoting safe, timely, and affordable access to evidence-based care for patients; enhancing efficiency; and reducing administrative burdens. The prior authorization process can be burdensome for all involved—health care providers, health plans, and patients. Yet, there is wide variation in medical practice and adherence to evidence-based treatment. Communication and collaboration can improve stakeholder understanding of the functions and challenges associated with prior authorization and lead to opportunities to improve the process, promote quality and affordable health care, and reduce unnecessary burdens.

The following five areas offer opportunities for improvement in prior authorization programs and processes that, once implemented, can achieve meaningful reform.

- 1. Selective Application of Prior Authorization.** Differentiating the application of prior authorization based on provider performance on quality measures and adherence to evidence-based medicine or other contractual agreements (i.e., risk-sharing arrangements) can be helpful in targeting prior authorization requirements where they are needed most and reducing the administrative burden on health care providers. Criteria for selective application of prior authorization requirements may include, for example, ordering/prescribing patterns that align with evidence-based guidelines and historically high prior authorization approval rates.

We agree to:

- *Encourage the use of programs that selectively implement prior authorization requirements based on stratification of health care providers' performance and adherence to evidence-based medicine*
- *Encourage (1) the development of criteria to select and maintain health care providers in these selective prior authorization programs with the input of contracted health care providers and/or provider organizations; and (2) making these criteria transparent and easily accessible to contracted providers*

- *Encourage appropriate adjustments to prior authorization requirements when health care providers participate in risk-based payment contracts*
- 2. Prior Authorization Program Review and Volume Adjustment.** Regular review of the list of medical services and prescription drugs that are subject to prior authorization requirements can help identify therapies that no longer warrant prior authorization due to, for example, low variation in utilization or low prior authorization denial rates. Regular review can also help identify services, particularly new and emerging therapies, where prior authorization may be warranted due to a lack of evidence on effectiveness or safety concerns.

We agree to:

- *Encourage review of medical services and prescription drugs requiring prior authorization on at least an annual basis, with the input of contracted health care providers and/or provider organizations*
 - *Encourage revision of prior authorization requirements, including the list of services subject to prior authorization, based on data analytics and up-to-date clinical criteria*
 - *Encourage the sharing of changes to the lists of medical services and prescription drugs requiring prior authorization via (1) provider-accessible websites; and (2) at least annual communications to contracted health care providers*
- 3. Transparency and Communication Regarding Prior Authorization.** Effective, two-way communication channels between health plans, health care providers, and patients are necessary to ensure timely resolution of prior authorization requests to minimize care delays and clearly articulate prior authorization requirements, criteria, rationale, and program changes.

We agree to:

- *Improve communication channels between health plans, health care providers, and patients*
 - *Encourage transparency and easy accessibility of prior authorization requirements, criteria, rationale, and program changes to contracted health care providers and patients/enrollees*
 - *Encourage improvement in communication channels to support (1) timely submission by health care providers of the complete information necessary to make a prior authorization determination as early in the process as possible; and (2) timely notification of prior authorization determinations by health plans to impacted health care providers (both ordering/rendering physicians and dispensing pharmacists) and patients/enrollees*
- 4. Continuity of Patient Care.** Continuity of patient care is vitally important for patients undergoing an active course of treatment when there is a formulary or treatment coverage

change and/or a change of health plan. Additionally, access to prescription medications for patients on chronic, established therapy can be affected by prior authorization requirements. Although multiple standards addressing timeliness, continuity of care, and appeals are currently in place, including state and federal law and private accreditation standards, additional efforts to minimize the burdens and patient care disruptions associated with prior authorization should be considered.

We agree to:

- *Encourage sufficient protections for continuity of care during a transition period for patients undergoing an active course of treatment when there is a formulary or treatment coverage change or change of health plan that may disrupt their current course of treatment*
- *Support continuity of care for medical services and prescription medications for patients on appropriate, chronic, stable therapy through minimizing repetitive prior authorization requirements*
- *Improve communication between health care providers, health plans, and patients to facilitate continuity of care and minimize disruptions in needed treatment*

- 5. Automation to Improve Transparency and Efficiency.** Moving toward industry-wide adoption of electronic prior authorization transactions based on existing national standards has the potential to streamline and improve the process for all stakeholders. Additionally, making prior authorization requirements and other formulary information electronically accessible to health care providers at the point-of-care in electronic health records (EHRs) and pharmacy systems will improve process efficiencies, reduce time to treatment, and potentially result in fewer prior authorization requests because health care providers will have the coverage information they need when making treatment decisions. Technology adoption by all involved stakeholders, including health care providers, health plans, and their trading partners/vendors, is key to achieving widespread industry utilization of standard electronic prior authorization processes.

We agree to:

- *Encourage health care providers, health systems, health plans, and pharmacy benefit managers to accelerate use of existing national standard transactions for electronic prior authorization (i.e., National Council for Prescription Drug Programs [NCPDP] ePA transactions and X12 278)*
- *Advocate for adoption of national standards for the electronic exchange of clinical documents (i.e., electronic attachment standards) to reduce administrative burdens associated with prior authorization*
- *Advocate that health care provider and health plan trading partners, such as intermediaries, clearinghouses, and EHR and practice management system vendors, develop and deploy software and processes that facilitate prior authorization automation using standard electronic transactions*
- *Encourage the communication of up-to-date prior authorization and step therapy requirements, coverage criteria and restrictions, drug tiers, relative*

costs, and covered alternatives (1) to EHR, pharmacy system, and other vendors to promote the accessibility of this information to health care providers at the point-of-care via integration into ordering and dispensing technology interfaces; and (2) via websites easily accessible to contracted health care providers