



August 12, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6082-NC
P.O. Box 8016
Baltimore, MD 21244-8016

Subject: Request for Information; Reducing Administrative Burden To Put Patients Over
Paperwork; RIN 0938-ZB54

Dear Administrator Verma:

The Regulatory Relief Coalition (the Coalition) is pleased to have the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Patients over Paperwork Request for Information (RFI), which was published in the *Federal Register* on June 11, 2019. The Coalition includes physician professional organizations dedicated to ensuring that Medicare patients have timely access to medically necessary services through the reduction in administrative burdens — including prior authorization (PA) — that divert physician focus away from patient care.

The Coalition applauds the Department of Health and Human Services' (HHS) focus on relieving the extraordinary regulatory burdens faced by physicians and other providers participating in the Medicare Program so as to improve Medicare beneficiaries' access to medically necessary health care services. We are encouraged by the agency's efforts to reduce administrative burdens imposed on providers under Medicare's Fee-for-Service programs. At the same time, however, PA requirements imposed by Medicare Advantage Organizations (MAOs) under the Medicare Advantage (MA) program pose the single greatest administrative burden for physicians caring for Medicare patients.

Over the past 10 years, health plans have increasingly used PA in an effort to reduce health care spending, substantially delaying medically necessary patient care and significantly increasing providers' administrative costs. Obtaining PA from various MA and other health plans typically require physicians or their staff to spend the equivalent of two or more days each week negotiating with insurance companies — time that would better be spent taking care of patients. For this reason, we are pleased that the Patients over Paperwork RFI issued in June specifically solicits recommendations for reducing the administrative burdens of, and access barriers posed by, the expanding use of PA.

Prior Authorization is Burdensome and Delays Care; Stakeholders Agree Change is Necessary

Nearly all respondents to a recent survey¹ conducted by the Regulatory Relief Coalition state that prior authorization causes delays in access to necessary care and the wait time for prior authorization can be lengthy. For most physicians (74%), it takes between 2 to 14 days to obtain prior authorization, but for 15%, this process can take from 15 to more than 31 days. A majority of physicians report that prior authorization causes patients to abandon treatment altogether, and, overwhelmingly (87%), physicians report that prior authorization has a negative impact on patient clinical outcomes. Most physicians (84%) report that the burden associated with prior authorization has significantly increased over the past five years as insurers have increased the use of prior authorization for procedures (84%); for diagnostic tools (78%); and for prescription medications (80%). The burden associated with prior authorization for physicians and their staff is now high or extremely high (92%), and in any given week, most physicians (42%) must contend with between 11 and 40 prior authorizations. Many physicians must now engage in the so-called peer-to-peer process — meaning after they go through an extensive paperwork process they must then speak directly to a clinician working for the health plan — to obtain prior authorization, and nearly 20% of respondents experience this requirement for 26-75% or more of their services. Moreover, in many cases, the health plan’s “peers” do not have the relative clinical background or expertise to assess the medical necessity of the service under review.

Health plan industry data also confirms the growing use of PA by MA plans. A recent study by Kaiser Family Foundation found that nearly four out of five MA enrollees (79%) are in plans that require prior authorization for some services in 2019.² Given the significant enrollment in MA plans — which now stands at one-third (34%) of all Medicare beneficiaries (22 million people) and is projected to rise to about 47 percent by 2029 — left unchecked, the burdens associated with PA will grow exponentially.

Fortunately, associations representing health plans, including the Association of Health Insurance Plans (AHIP) and Blue Cross Blue Shield Association (BCBSA), recognize the need to streamline and simplify prior authorization processes. Last year, these associations, along with leading national provider organizations, including the American Hospital Association (AHA), American Medical Association (AMA) and the Medical Group Management Association (MGMA), adopted the Consensus Statement on Improving the Prior Authorization Process,³ which sets forth principles for the design and implementation of PA programs.

Additionally, both patient groups and members of Congress have requested that the CMS address the barriers to access posed by PA under MA plans. In fact, over 40 patient and disability

¹ See Attachment A.

² Jacobson G, Freed M, Damico A, Neuman, T. A Dozen Facts About Medicare Advantage in 2019. Washington, DC: Kaiser Family Foundation, June 2019, <https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage-in-2019/> (accessed July 2019).

³ See Attachment B.

organizations and more than 100 members of Congress have requested that CMS address this issue.⁴ Furthermore, in June, legislation — H.R. 3107, the Improving Patients’ Timely Access to Care Act — was introduced in Congress. Supported by the Coalition, the common-sense reforms to the MA PA process included in this bill align with the aims of the above-referenced consensus statement. Among other things, this legislation would protect patients by establishing an electronic, real-time prior authorization process and minimize the use of prior authorization for routinely approved services. It also would provide essential patient protections for beneficiaries receiving medically-necessary and routinely approved care, allowing providers to focus more time on treating patients and less on bureaucratic hurdles. The provisions outlined in H.R. 3107 are PA reforms that CMS can, and should, implement.

RRC Recommendations

Our specific recommendations for reducing the administrative burden associated with the use of PA by MA plans are outlined in a letter dated September 27, 2018, to CMS Principal Deputy Administrator Demetrios Kouzoukas.⁵ In our letter, the Coalition requested that at a minimum CMS should, among other things, take the following actions:

- I. Issue Guidance to Plans.** CMS should issue a transmittal to MA plans that specifically adopts the policies for PA reform set forth in the Consensus Statement:
 - Selective Application of Prior Authorization
 - Prior Authorization Program Review and Volume Adjustment
 - Transparency and Communication Regarding Prior Authorization
 - Continuity of Patient Care
 - Automation to Improve Transparency and Efficiency
- II. Standardize PA Transactions.** CMS should finalize the Attachment Standard as soon as practicable and issue Model PA forms for PA submittals submitted via websites and manually.
- III. Collect Certain Data from Plans.** CMS should require MA plans to report on the extent of their use of PA including:
 - Data on the specific procedures and prescription medications subject to PA;
 - The proportion of each service and prescription medication approved; and
 - The time elapsed from submission until the issuance of an organization determination (i.e., authorization for coverage and payment for a health care item or service).
- IV. Exercise Ongoing Oversight.** CMS should exercise ongoing oversight over MA plans’ PA processes, which should be reviewed based on clear criteria. MAO performance data

⁴ See Attachments C and D.

⁵ See Attachment E.

should be made public on the CMS website based on information gathered through MA plan annual reports and special focus audits.

We believe that CMS plays a critical role in ensuring that these principles become the industry standard, ultimately benefiting patients, providers, health plans, and the Medicare program alike. Thus, the RRC strongly urges CMS to adopt these recommendations as soon as practicable. We believe that the agency could take no stronger action to further the objectives of the Patients over Paperwork initiative than to address the enormous administrative burden and barriers to care posed by the growing application of PA.

Thank you for considering our comments.

Sincerely yours,

American Academy of Neurology
American Academy of Ophthalmology
American Association of Neurological Surgeons
American College of Cardiology
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Society of Clinical Oncology
American Urological Association
Congress of Neurological Surgeons



Prior Authorization Survey Top-Line Results

Patient Access to Care Has Been Impacted

- Eighty-two percent of respondents state that prior authorization either always (37%) or often (45%) **delays access** to necessary care.
- The **wait time** for prior authorization can be lengthy. For most physicians (74%) it takes between 2 to 14 days to obtain prior authorization, but for 15%, this process can take from 15 to more than 31 days.
- Prior authorization causes patients to **abandon treatment** altogether with 32% reporting that patients often abandon treatment and 50% reporting that patients sometimes abandon treatment.
- Overwhelmingly (87%), physicians report that prior authorization has a significant (40%) or somewhat (47%) **negative impact** on patient **clinical outcomes**.
- Three-quarters (74%) reported that during the past five years, stable patients had been asked to **switch medications** by the health plan even though there was no medical reason to do so.

Prior Authorization Burden Has Increased

- Eight-four percent of physicians report that the **burden** associated with prior authorization has **significantly increased** over the past five years.
- Insurers have increased the use of prior authorization over the past years for **procedures** (84%); for **diagnostic tools** (78%); and for **prescription medications** (80%).
- The burden associated with prior authorization for physicians and their staff is **high** or **extremely high** (92%).
- In any given week, most physicians (42%) must contend with between 11 and 40 prior authorizations. One-fifth of respondents face more than 40 per week.
- Many physicians must now engage in the so-called **peer-to-peer process** to obtain prior authorization, and nearly 20% of respondents experience this requirement for 26 to 75% or more of their services (including prescription drugs, diagnostic tests and medical services).
- Ultimately, the **majority of services are approved** (71%), with one-third of physicians getting approved 90% or more of the time.
- Unbelievably, despite gaining prior authorization, insurance companies **deny payment** after services are rendered, an outcome three-fifths of physicians have experienced more than once in the past year, and 16% have had this happen 20 or more times.
- Nearly three-fifths (59%) of physicians have staff members working **exclusively** on prior authorization, with most staff spending between 10-20 hours per week on prior authorization.
- **Most plans** employ prior authorization, although UnitedHealthcare (68%), Blue Cross Blue Shield (66%) and Aetna 61%) are the top utilizers.

Demographics

- Medical specialties participating include: Dermatology, Neurosurgery, Obstetrics & Gynecology, Ophthalmology, Orthopaedic Surgery, Otolaryngology, Plastic Surgery and Urology
- Forty-one percent of respondents are from the South; 19% from the Northeast; 24% from the Midwest; and 16% from the West and U.S. Territories.
- Nearly one-third (60%) of respondents are in private practice; 9% are in private practice with an academic affiliation; 17% are in academic practice; and 12% are employed by a hospital or health system.
- Twenty percent of respondents are in solo practice; 29% are in a small group (2-5 physicians) single specialty practice; 22% are in a medium (6-20 physicians) group single specialty practice; 9% are in a large group (21+) single specialty practice; and the remainder are in multi-specialty group practices.
- Forty-five percent of respondents practice in an urban setting; 44% practicing in a suburban setting; while only 11% are in rural practice.

Regulatory Relief Coalition

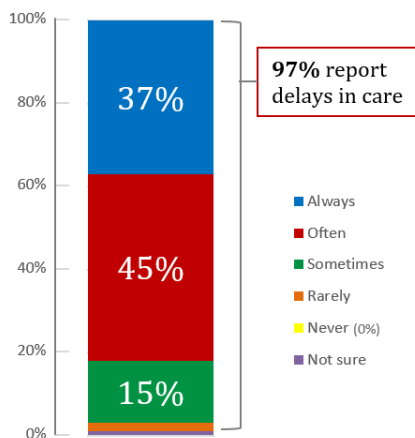
Prior Authorization Survey

Prior Authorization is Putting Patients at Risk and Increasing Physician Burden

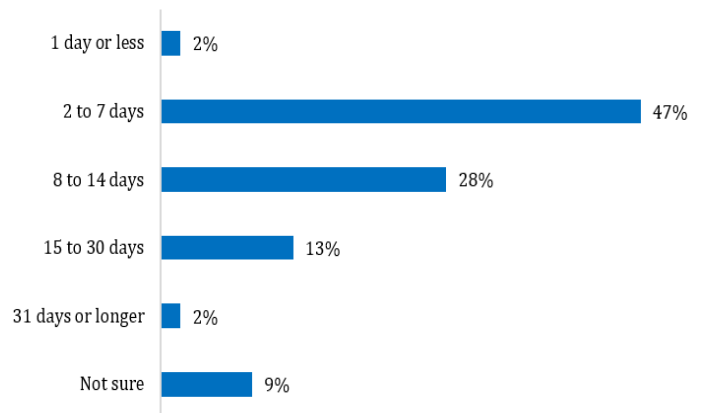
Patient Access to Care Has Been Adversely Impacted

Nearly all respondents state that prior authorization causes **delays in access** to necessary care, and the **wait time** for prior authorization can be lengthy. For most physicians (74%) it takes between 2 to 14 days to obtain prior authorization, but for 15%, this process can take from 15 to more than 31 days.

Q. For those patients whose treatment requires prior authorization, how often does this process delay access to necessary care?

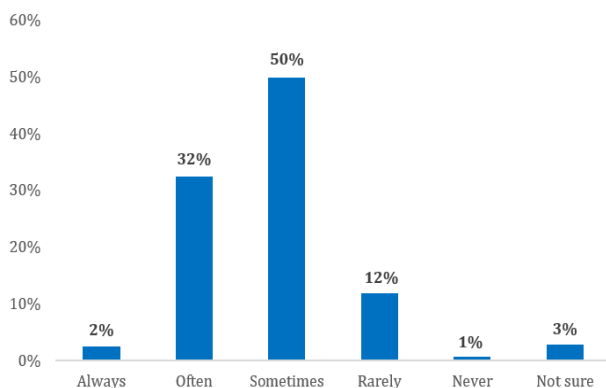


Q. What is the average length of time to obtain prior authorization after all required documentation has been submitted?

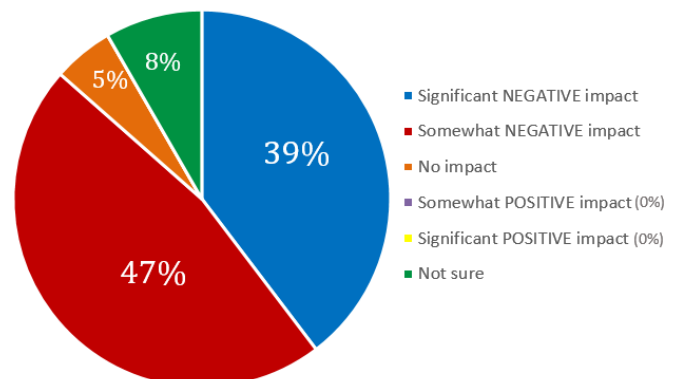


A majority of physicians reported that prior authorization causes patients to **abandon treatment** altogether. Similarly, three-quarters (74%) of respondents reported that during the past five years, stable patients had been asked to **switch medications** by the health plan even though there was no medical reason to do so. Overwhelmingly (87%), physicians report that prior authorization has a **negative impact** on patient **clinical outcomes**.

Q. For those patients whose treatment requires prior authorization, how often do issues related to this process lead to patients abandoning their recommended course of treatment?



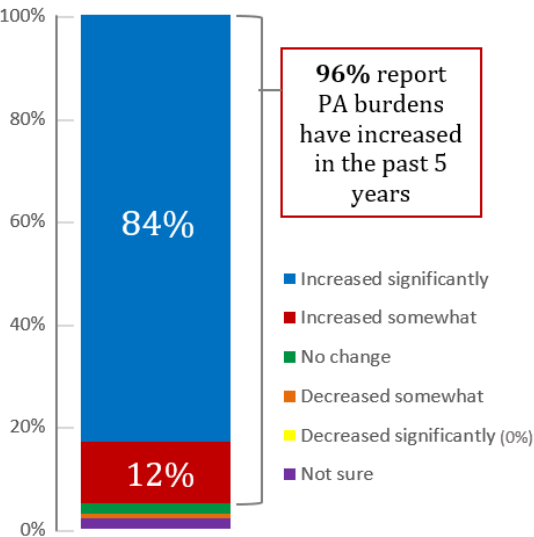
Q. For those patients whose treatment requires prior authorization, what is the impact of this process on patient clinical outcomes?



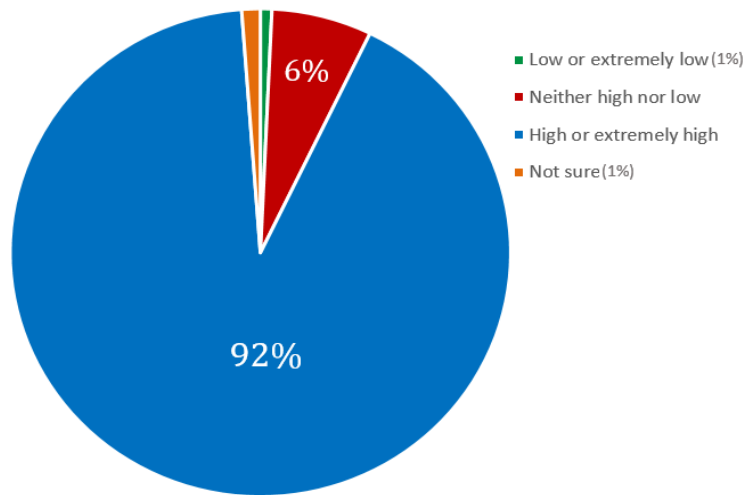
The Burden of Prior Authorization on Physicians Has Increased

Most physicians (84%) report that the **burden** associated with prior authorization has **significantly increased** over the past five years as insurers have increased the use of prior authorization for procedures (84%); for diagnostic tools (78%); and for prescription medications (80%). The burden associated with prior authorization for physicians and their staff is now **high** or **extremely high** (92%).

Q. How has the burden associated with prior authorization changed over the last five years for the physicians and staff in your practice?

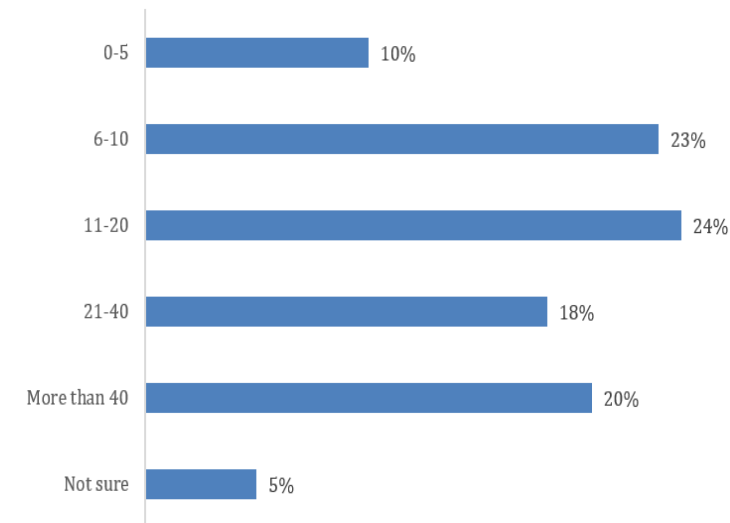


Q. How would you describe the burden associated with prior authorization for the physicians and staff in your practice?



In any given week, most physicians (42%) must contend with between 11 and 40 prior authorizations. One-fifth of respondents face more than 40 per week. Many physicians must now engage in the so-called **peer-to-peer** process — meaning after they go through an extensive paperwork process they must first speak directly to a clinician working for the health plan— to obtain prior authorization, and nearly 20% of respondents experience this requirement for 26-75% or more of their services (including prescription drugs, diagnostic tests and medical services).

Q. Please provide your best estimate of the number of prior authorizations (total for prescription medicine, diagnostic tests and medical services) completed by yourself and/or your staff for your patients in the last week.



20% of physicians go to “peer-to-peer” review for **26-75%** or more of their prior authorizations—and frequently the reviewer is not in the same or similar specialty



Ultimately, the **majority of services are approved** (71%), with one-third of physicians getting approved 90% or more of the time. Unbelievably, despite gaining prior authorization, insurance companies **deny payment after services are rendered**, an outcome three-fifths of physicians have experienced more than once in the past year, and 16% have had this happen 20 or more times.

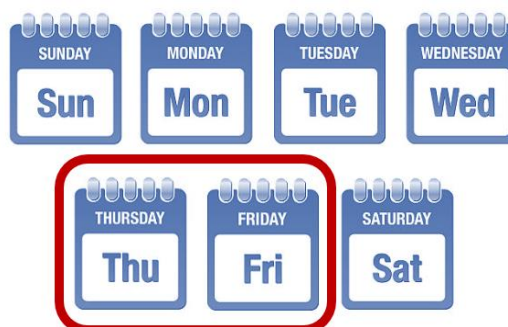
Prior Authorization has a significant impact on the **costs of practice**

59%



Nearly three-fifths of physicians have staff members **working exclusively** on prior authorization

Physicians and their staff spend the equivalent of at least **two days** on prior authorization each week.



Survey Methodology

A 27-question, web-based survey was administered from November 2018 through January 2019. Survey invitations were sent to physicians via email. 1,602 physicians from the following medical specialties participated: Dermatology, Neurosurgery, Obstetrics & Gynecology, Ophthalmology, Orthopaedic Surgery, Otolaryngology, Plastic Surgery and Urology.

Forty-one percent of respondents are from the South; 19% from the Northeast; 24% from the Midwest; and 16% from the West and U.S. Territories. Nearly one-third (60%) of respondents are in private practice; 9% are in private practice with an academic affiliation; 17% are in academic practice; and 12% are employed by a hospital or health system. Twenty percent of respondents are in solo practice; 29% are in a small group (2-5 physicians) single specialty practice; 22% are in a medium (6-20 physicians) group single specialty practice; 9% are in a large group (21+) single specialty practice; and the remainder are in multi-specialty group practices. Forty-five percent of respondents practice in an urban setting; 44% practicing in a suburban setting; while only 11% are in rural practice.

About the Regulatory Relief Coalition

The Regulatory Relief Coalition is a group of eight national physician specialty organizations advocating for a reduction in Medicare program regulatory burdens to protect patients' timely access to care and allow physicians to spend more time with their patients. Members include: American Academy of Neurology, American Academy of Ophthalmology, American Association of Neurological Surgeons, American College of Cardiology, American College of Rheumatology, American College of Surgeons, American Urological Association, and Congress of Neurological Surgeons.

More Information

For more information about the Regulatory Relief Coalition's prior authorization survey, please contact:

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American Association of Neurological Surgeons/
Congress of Neurological Surgeons
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Washington, DC 20001
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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

Patient and Disability Organizations Expressing Concern about the use of PA in the Medicare Advantage Program 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

March 22, 2018

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

Dear Administrator Verma:

On behalf of the patient organizations listed below, we are writing to ask that CMS eliminate the administrative barriers to patient access to medically necessary services that are imposed by Medicare Advantage plans' increasing prior authorization requirements. We are greatly concerned that patients enrolled in Medicare Advantage and other managed care plans throughout the country are facing growing barriers to timely access to care that are caused by onerous and often unnecessary prior authorization requirements.

While we understand that some insurers' prior approval requirements may be necessary in order to ensure that the care that is provided is medically necessary, we are concerned that many prior approval requirements routinely imposed by Medicare Advantage and other health plans are difficult to justify on this basis. For example, many plans maintain prior approval requirements for items and services that are routinely approved, thus delaying medically necessary care without any cost savings to the plan. Prior approval requirements are especially difficult to understand when they are imposed on services, such as access to transplantation, surgery for blinding eye disease, or cancer care, that are very unlikely to be over-utilized and that require timely access. We are especially troubled by reports that some managed care plans engage benefits management companies that are paid based on the number or cost of the services they deny.

It appears that private insurers are beginning to focus on ways to limit the negative impact of prior approval requirements without subjecting enrollees to medically unnecessary services. We urge CMS to focus on this area as well, to ensure that prior approval requirements do not impose inappropriate barriers to coverage for the increasing number of Medicare beneficiaries who opt to enroll in Medicare Advantage plans.

We ask you to consider increasing CMS' oversight over Medicare Advantage plans' use of prior authorization. We also request CMS to instruct these plans to limit the use of prior authorization to those services that are demonstrably over-utilized, to review their prior authorization lists at least annually, and to ensure that patient materials include full disclosure of any prior authorization requirements. We believe that taking these steps will help the increasing proportion of Medicare beneficiaries who are enrolled in these plans to obtain medically necessary care in a timely manner.

Sincerely yours,

ALS Association
American Macular Degeneration Foundation
Arthritis Foundation
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



March 23, 2018

VIA ELECTRONIC MAIL

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: **Extensive Use of Prior Authorization in Medicare Advantage Plans Restricts Access to Medical Rehabilitation for Medicare Beneficiaries**

Dear Administrator Verma:

The undersigned members of the Coalition to Preserve Rehabilitation (“CPR”) write to ask the Centers for Medicare and Medicaid Services (CMS) to eliminate the administrative barriers to patient access to medically necessary rehabilitation services and devices that are often imposed through the use of prior authorization in Medicare Advantage (MA) plans. CPR is greatly concerned that prior authorization requirements in MA plans may be sources of increasing barriers to accessing needed care, particularly inpatient and outpatient rehabilitation services and devices, for beneficiaries nationwide.

CPR is a coalition of national consumer, clinician, and membership organizations that advocate for policies to ensure access to rehabilitative care so that individuals with injuries, illnesses, disabilities and chronic conditions may regain and/or maintain their maximum level of health and independent function. CPR is comprised of organizations that represent beneficiaries who are frequently inappropriately denied access to rehabilitative care in a variety of settings, as well as the providers who serve them.

Medicare Advantage served almost 19 million Medicare beneficiaries in 2017 comprising 32 percent of the total Medicare population, according to MedPAC. MA plans were paid approximately \$210 billion in this same year. By 2028, MedPAC estimates that 32 million beneficiaries will participate in the MA program. The fast pace of growth of this program suggests the need for greater scrutiny of mechanisms imposed by these plans to manage service utilization, such as prior authorization.

While prior authorization requirements may be appropriate in some limited circumstances to ensure that patients are receiving medically necessary care, the use of such requirements has become increasingly routine in MA plans. Often, the use of prior authorization in these

circumstances is difficult to justify. Many plans utilize prior authorization processes for items and services that are routinely approved. Additionally, the use of prior authorization to approve care including rehabilitation services and devices, transplantation, non-elective surgeries, and cancer care is especially hard to justify, given that these and many similar medical services are unlikely to be over-utilized and often need to be provided in a timely manner in order to maximize their medical efficacy.

In these cases and others, prior authorization often serves as an unnecessary delay for beneficiaries seeking medically necessary care, and often results in no cost savings to the plan. CPR is especially troubled to have learned of reports of some managed care plans' use of benefits management companies that are incentivized based on the number or dollar amount of services they deny.

Federal law states that MA beneficiaries are entitled to the same benefits available under Medicare fee-for-service (FFS). (*See id.* § 422.100(f)(1)-(3).) Medicare regulations also stipulate that MA Plans must comply with FFS coverage guidelines and national and local coverage determinations subject to limited exceptions for coverage uniformity across geographic areas. (*See*, 42 C.F.R. § 422.101(b)(2).) Rather than abiding by Medicare coverage criteria, MA plans typically impose prior authorization and utilize proprietary admission or coverage guidelines, such as those marketed by Milliman and Interqual, to justify a denial of rehabilitation coverage.

These guidelines often contradict well-established best practices in medicine, such as the American Heart Association and American Stroke Association's (AHA/ASA) guidelines for stroke recovery. AHA/ASA "strongly recommends that stroke patients be treated at an in-patient rehabilitation facility rather than a skilled nursing facility." In fact, the Medicare Payment Advisory Commission found that 2015 MA admissions to inpatient rehabilitation hospitals were one third of admissions to this same setting under Medicare fee-for-service. (*See*, MEDPAC, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY, p. 298 (Mar. 2017).

Recently, private insurers have begun focusing on ways to limit the negative impact of prior authorization on access to medically necessary care while ensuring beneficiaries do not receive medically unnecessary services. CPR urges CMS to consider implementing similar policies in MA plans as well, to ensure that prior authorization processes do not prevent beneficiaries who elect to participate in MA plans from accessing needed care, especially rehabilitation services and devices in both the inpatient and outpatient settings.

To do so, CPR recommends that CMS increase oversight of the use of prior authorization in MA plans. Such oversight should include stronger directives to MA plans to limit the use of prior authorization to services that are demonstrably over-utilized. CMS should also review the list of services that each MA plan subjects to prior authorization, prohibit the use of proprietary coverage guidelines as a substitute for fee-for-service coverage criteria, and ensure that MA beneficiaries are provided with comprehensive information disclosing the use of prior authorization in their plan.

CPR appreciates the opportunity to comment on the use of prior authorization in MA plans. For more information, please contact Peter Thomas, coordinator for CPR by e-mailing Peter.Thomas@PowersLaw.com or by calling 202-466-6550.

Sincerely,

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

Congress of the United States
Washington, DC 20515

October 10, 2018

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

Dear Administrator Verma:

As you and your staff work to reduce barriers to patient care through your Patients over Paperwork initiative, we are writing to request that you improve how prior authorization (PA) works under Medicare Advantage (MA). We are concerned that patients may be encountering barriers to timely access to care that are caused by onerous and often unnecessary prior authorization requirements. Therefore, we request your agency provide guidance to MA plans regarding the use of prior authorization to ensure that these requirements do not create inappropriate barriers to care for Medicare patients.

We recognize the important role that MA plays in the Medicare program and understand that utilization review tools such as PA can sometimes play a role in ensuring patients receive clinically appropriate treatment while controlling costs. However, we hear from physicians and other health care providers in our districts about the growing administrative burdens associated with PA requirements. Because MA plans are ultimately required to provide equivalent coverage to fee-for-service (FFS) Medicare, which generally does not require pre-approval for services, plans are precluded from using PA to inhibit access to services.

It is our understanding that some plans require repetitive prior approvals for patients that are not based on evidence and may delay medically necessary care. Many of these PA requirements are for services or procedures performed in accordance with an already-approved plan of care, as part of appropriate, ongoing therapy for chronic conditions, or for services with low PA denial rates. We request you issue guidance to MA plans dissuading practices such as these and provide direction to increase transparency, streamline PA and minimize the impact on patients.

More generally, we understand that CMS monitors enrollee access as part of its oversight. We believe it would be helpful for CMS to collect data on the scope of PA practices – including denial, delay and approval rates. Additionally, we request a report describing CMS oversight of pre-approval policies in MA plans, the use of PA for Part A and Part B services and descriptions of audit protocols that focus on this area.

Finally, key stakeholders have worked together to identify opportunities to improve the PA process, promote patient access to timely care and reduce unnecessary administrative burdens. We request that you and your staff engage with these organizations on additional opportunities to improve the PA process for all stakeholders.

Thank you for your consideration of these requests.

Sincerely,



David P. Roe, M.D.
Member of Congress



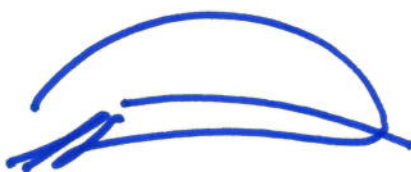
Ami Bera, M.D.
Member of Congress



Andy Harris, M.D.
Member of Congress




Neal P. Dunn, M.D.
Member of Congress



Scott DesJarlais, M.D.
Member of Congress



Roger Marshall, M.D.
Member of Congress



Larry Bucshon, M.D.
Member of Congress



Raul Ruiz, M.D.
Member of Congress




Brian Babin, D.D.S.
Member of Congress



Ralph Abraham, M.D.
Member of Congress


Yvette Clarke
Member of Congress


Pete Sessions
Member of Congress


Raúl M. Grijalva
Member of Congress


Derek Kilmer
Member of Congress



Brian Fitzpatrick
Member of Congress


Andy Barr
Member of Congress



Tom Cole
Member of Congress



Rod Blum
Member of Congress


Mike Coffman
Member of Congress


Julia Brownley
Member of Congress


Andy Biggs
Member of Congress


Peter T. King
Member of Congress


Mark DeSaulnier
Member of Congress


Lucille Roybal-Allard
Member of Congress



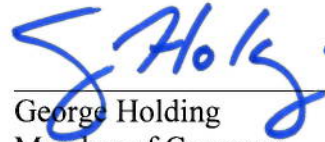
Mike Gallagher
Member of Congress



H. Morgan Griffith
Member of Congress



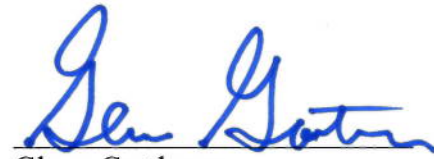
James R. Langevin
Member of Congress



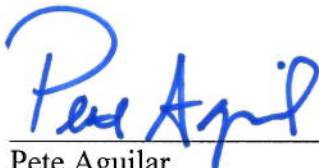
George Holding
Member of Congress



John Garamendi
Member of Congress



Glenn Grothman
Member of Congress



Pete Aguilar
Member of Congress



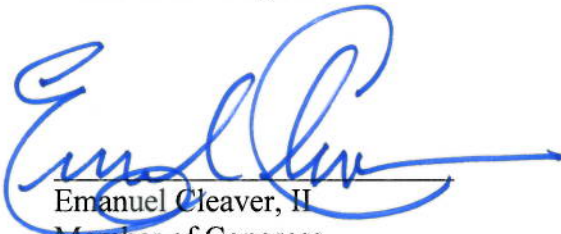
John J. Duncan, Jr.
Member of Congress



C. A. Dutch Ruppersberger
Member of Congress



André Carson
Member of Congress



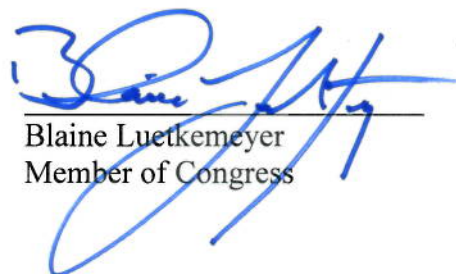
Emanuel Cleaver, II
Member of Congress



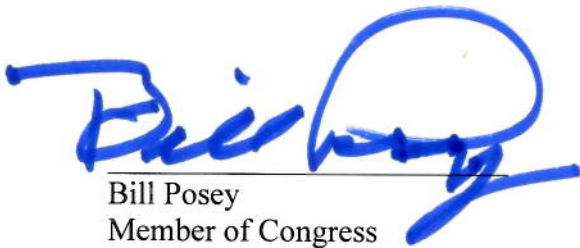
Collin Peterson
Member of Congress



Bill Shuster
Member of Congress



Blaine Luetkemeyer
Member of Congress



Bill Posey
Member of Congress




Mike Bost
Member of Congress



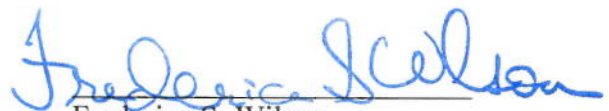
Rick W. Allen
Member of Congress




Rodney Davis
Member of Congress



Salud O. Carbajal
Member of Congress



Frederica S. Wilson
Member of Congress



Josh Gottheimer
Member of Congress



Garret Graves
Member of Congress



Sheila Jackson Lee
Member of Congress



Robert E. Latta
Member of Congress



Colleen Hanabusa
Member of Congress



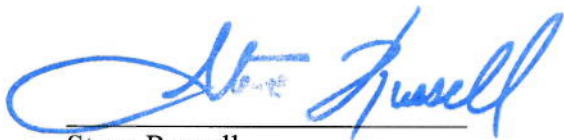
Betty McCollum
Member of Congress



Michelle Lujan Grisham
Member of Congress



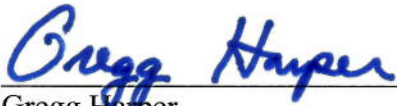
Jason Smith
Member of Congress



Steve Russell
Member of Congress




Glenn "GT" Thompson
Member of Congress



Gregg Harper
Member of Congress



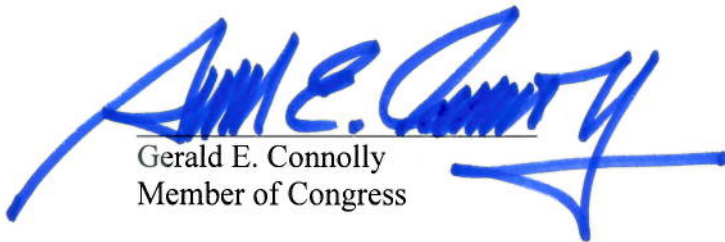
Gus M. Bilirakis
Member of Congress



Barry Loudermilk
Member of Congress



Peter Welch
Member of Congress



Gerald E. Connolly
Member of Congress



Kevin Cramer
Member of Congress



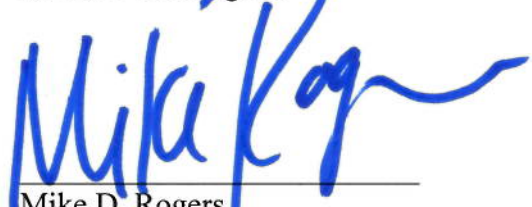
Paul Tonko
Member of Congress



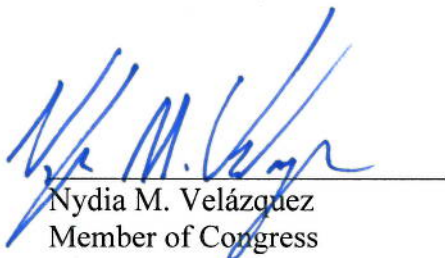
Jaime Herrera Beutler
Member of Congress



Walter Jones
Member of Congress




Mike D. Rogers
Member of Congress




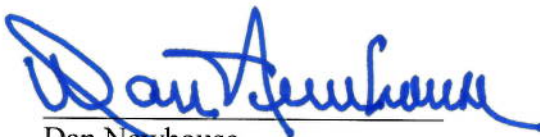
Nydia M. Velázquez
Member of Congress



Mark Pocan
Member of Congress



David B. McKinley, P.E.
Member of Congress


Brian Higgins
Member of Congress

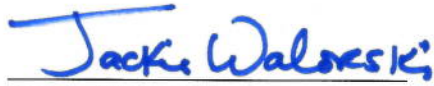

Dan Newhouse
Member of Congress



Joe Wilson
Member of Congress


James Comer
Member of Congress


Lloyd Doggett
Member of Congress


Vicky Hartzler
Member of Congress



Jackie Walorski
Member of Congress


Adam B. Schiff
Member of Congress

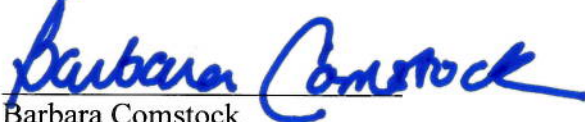
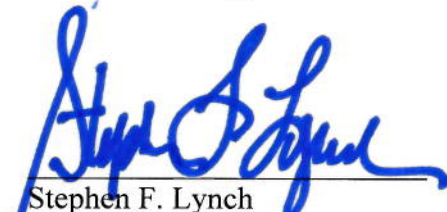


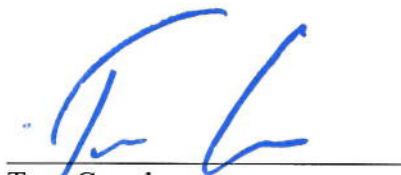

Alcee L. Hastings
Member of Congress


John R. Moolenaar
Member of Congress


Ann Wagner
Member of Congress


William Lacy Clay
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French Hill
Member of Congress


John B. Larson
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Rick Larsen
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Barbara Comstock
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Chellie Pingree
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Steve Pearce
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Jody Hice
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Martha Roby
Member of Congress
Peter A. DeFazio
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Trey Gowdy
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Rosa L. DeLauro
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Dave Loebsack
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Marcy Kaptur
Member of Congress
David Scott
Member of Congress



Tulsi Gabbard
Member of Congress



Brendan F. Boyle
Member of Congress



Tim Walz
Member of Congress



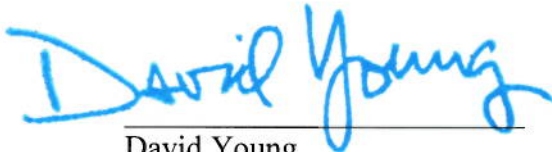
Alma S. Adams, Ph.D.
Member of Congress



Ken Buck
Member of Congress



Jimmy Gomez
Member of Congress



David Young
Member of Congress



Grace Meng
Member of Congress



Anna G. Eshoo
Member of Congress



September 27, 2018

Demetrios Kouzoukas
Principal Deputy Administrator & Director of the Center for Medicare
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Kouzoukas:

On behalf of the Regulatory Relief Coalition, including the professional associations set forth below, thank you for taking the time to meet with us on September 5, 2018. We are encouraged to hear that you and your staff are taking a closer look at what CMS might do to improve prior authorization (PA) for the patients our physicians serve and the physicians our organizations represent. Per your recent request, and as outlined in our comments, correspondence, and meetings with CMS, we believe that these issues should be addressed by taking the four actions set forth below.

I. GUIDANCE TO PLANS: CMS should issue guidance urging MA plans to follow the PA practices endorsed by America's Health Insurance Plans (AHIP) and Blue Cross/Blue Shield Association (BC/BSA) and to adhere to applicable Medicare regulatory requirements.

In January 2018, associations representing managed care plans (AHIP and BC/BSA) endorsed a statement of principles¹ that identifies five areas that “offer opportunities for improvement in prior authorization programs and processes that, once implemented, can achieve meaningful reform.” These include, among other things:

- Selective Application of PA: MA plans should apply PA requirements selectively, exempting providers that meet evidence-based guidelines.
- Annual PA Program Review and Removal of Services for which PA is Unnecessary: Services involving low variation in utilization or low PA denial rates should be removed from PA lists.
- Assuring Continuity of Care: MA plans should minimize repetitive PA requirements for chronic conditions.

We urge CMS to issue a transmittal to MA plans that (a) specifically adopts the policies for PA reform set forth in the Consensus Statement; and (b) “flags” PA practices that will be considered inappropriate barriers to access.²

¹ Consensus Statement on Improving the Prior Authorization Process (*See attached*).

² These include, for example, implementing PA policies that are inconsistent with local or national LCDs; requiring repetitive PA for chronic conditions; requiring PA for items and services that are part of a plan of care that has already been approved; denying payment for failure to obtain PA for a service that is performed during the course of an approved surgical procedure.)

The transmittal should also remind MA plans that they may not subsequently deny payment for a service that has been approved through a PA process, since the PA decision should resolve all issues related to payment.”

II. STANDARIZATION OF PA TRANSACTIONS: CMS should finalize the Attachment Standard as soon as practicable and issue Model PA forms for PA submittals submitted via websites and manually.

As you know, the administrative burden of PA processes is in part attributable to the lack of a uniform format for the submission of PA requests. To facilitate uniformity, we urge CMS to issue the Attachment Standard (278) as soon as practicable. We note, however, that, in order to alleviate their own administrative burdens pending the issuance of the Attachment Standard, MA plans are establishing their own proprietary websites, which are not subject to HIPAA transaction standards, but are required to mirror the content required by the transaction standards. In the absence of oversight or guidance, MA plans’ website tools — like their manual submittal processes — are individualized and idiosyncratic. We urge CMS to issue Model PA Forms to be utilized in conjunction with MA plans’ PA websites (direct data entry systems) and for manual submissions.

III. DATA COLLECTION: CMS should require MA plans to report on the extent of their use of PA and the approval/denial rate by service and/or prescription medications.

Reasonable resolution of provider and patient grievances with respect to PA requires comprehensive and specific information regarding MA plans’ PA processes and outcomes. This should include the submission of the following data as one component of MA plans’ annual reports to CMS:

- Data on the specific procedures and prescription medications subject to PA;
- The proportion of each service and prescription medication approved; and
- The time elapsed from submission until the issuance of an organization determination.

Without this data, CMS policymaking or congressional oversight necessarily would be formulated “in the dark.”

IV. OVERSIGHT: CMS should exercise ongoing oversight over MA plans PA processes.

Without enhanced CMS oversight over MA plans’ PA processes, it is doubtful whether any meaningful progress will be achieved. MA plans’ PA processes should be reviewed based on clear criteria and their performance made public on the CMS website, based on information gathered through:

- MA plan annual reports; and
- Special focus audits.

We would be delighted to work with you on the criteria we believe would be of interest to patients and providers.

We look forward to hearing from you soon regarding the actions that CMS intends to take regarding this important issue.

Sincerely yours,

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 Urological Association
American Society of Clinical Oncology

Enclosure



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