



National Health Council

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BY ELECTRONIC DELIVERY

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244-8013

RE: Request for Information: Reducing Administrative Burden to Put Patients over Paperwork

Dear Administrator Verma:

The National Health Council (NHC) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS') Request for Information entitled "Reducing Administrative Burden to Put Patients over Paperwork."

Founded in 1920, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. The NHC provides a united voice for the more than 160 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 125 diverse national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient advocacy organizations, which control its governance and policy-making process. Other members include health-related associations and nonprofit organizations including the provider, research and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic, and payer organizations.

The NHC supports policy changes and refinements that reduce the burden patients and providers face in making treatment decisions and accessing care that best aligns with the patient's health care needs and goals. Individuals with chronic diseases and disabilities and their providers face greater overall burden within the health care ecosystem than healthier individuals due to the lifelong management of their condition. With the cost of treating and managing chronic conditions being significant and increasing,¹ initiatives to reduce the overall costs

¹ STATISTICAL BRIEF #506: Concentration of Health Expenditures and Selected Characteristics of High Spenders, U.S. Civilian Noninstitutionalized Population, 2015, Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey, https://meps.ahrq.gov/data_files/publications/st506/stat506.shtml

of care for the Medicare program tend to focus on higher-cost items and services individuals with chronic conditions rely upon to maintain their health and quality of life. These initiatives have often been associated with new or increased hurdles and paperwork burdens that fall disproportionately on complex patients and their treating physicians, complicating continued access to care.

The NHC continues to support thoughtful reforms and policy refinements that promote efficiency, reduce paperwork burden, contain costs, and drive higher-quality care for all Americans. Our comments focus on reducing the burden individuals with chronic conditions and their providers experience in starting or continuing treatment plans that align with the patient's health care goals.

The NHC applauds CMS' beneficiary engagement activities and urges the Agency to expand this important work with an eye toward ensuring representativeness of individuals with chronic diseases and disabilities.

The NHC appreciates CMS' commitment to transforming the health care delivery system and shares its stated goal of putting an increased focus on patient-centered care, innovation, and outcomes. We agree that when providers spend less time on paperwork and more time on the clinician-patient relationship, patients have a greater opportunity for improvement in the health care outcomes that are most important to them.

We have supported the goals of CMS' Patients over Paperwork initiative since its launch in 2017 and commend the Agency for its stakeholder-inclusive approach to identifying "opportunities to modernize or eliminate rules and requirements that are outdated, duplicative, or getting in the way of good patient care."² In particular, we expect that CMS' ongoing direct education and outreach to providers and beneficiaries through onsite engagements has enabled a better understanding of the real-world impact CMS' requirements have on clinician workflow and decision making. We appreciate CMS' commitment to continuing this "fieldwork," and urge the Agency to consider expansion of and refinements to its outreach efforts that would improve the "representativeness" of the feedback, particularly with respect to inclusion of subpopulations of patients with chronic conditions and disabilities. Similarly, we urge CMS to leverage these Patients over Paperwork outreach initiatives to inform decisions and policy refinements under consideration for reducing Medicare costs. This would better arm CMS with the information needed to ensure Medicare's most vulnerable patients, and their providers are not disproportionately and adversely impacted.

As a voice for individuals with chronic diseases and disabilities, the NHC devotes significant attention to devising and improving mechanisms for engaging patients and incorporating their perspectives into policies and decisions likely to impact availability of and access to high-quality medical care. We believe that effective, meaningful patient engagement and outreach requires inclusion of patients, including caregivers,

² <https://www.regulations.gov/document?D=CMS-2019-0084-0001>

advocates, and advocacy organizations, that are *representative*³ of the target patient community.

Information Request: Improve the accessibility and presentation of CMS requirements for quality reporting, coverage, documentation, or prior authorization.

Prior authorization and other utilization management tools

The NHC has previously voiced its concerns with CMS' new policies expanding the use of utilization management tools such as step therapy, prior authorization, and differential cost sharing. Although we greatly appreciate that CMS added additional patient protections to its step-therapy policy announced in sub-regulatory guidance in August 2018,⁴ we remain concerned that a potentially significant portion of any resulting cost savings may be associated with impeding access rather than the intended goal of ensuring appropriate utilization.

We continue to hear from provider organizations in our membership that their members find processes associated with prescribing treatments to be sufficiently onerous to require increased staffing and/or result in them taking time away from their patient-care duties to navigate documentation, reconsideration, and appeals processes. Although CMS' new policies on utilization management were not intended to impact the statutory requirement that Medicare Advantage (MA) plans provide the same coverage that is available in traditional Medicare, clinicians encounter increased denials of Part B covered therapies.

The NHC is concerned that unless CMS directs paperwork-burden reduction strategies toward the unique needs of individuals with chronic diseases and disabilities, these patients will increasingly encounter difficulties finding providers willing to deal with the series of prior authorization requests, documentation requirements, and coverage denials that are becoming an inevitable part of managing their conditions.

We urge CMS to:

- Ensure that patients do not have to repeatedly “clear” prior authorization and step-therapy hurdles each year or each time they change plans;
- Require Part D plans to have a distinct formulary committee for Medicare's elderly and disabled populations;
- Require that Part D formulary committees have a clinical expert for each therapeutic area it seeks to limit, as well as experts in geriatrics and care for disabled populations;

³<https://www.nationalhealthcouncil.org/sites/default/files/Representativeness%20in%20Patient%20Engagement.pdf>

⁴<https://thehill.com/blogs/congress-blog/healthcare/454726-medicare-advantage-and-part-d-rule-a-win-for-patients-but-out>

- Increase Part D and MA plan accountability for utilization-management tools by reducing opportunities for PBMs to generate a revenue stream for implementing them (e.g., add-on fees for processing each prior authorization request, and disincentivize utilization-management tools that trigger high levels of exception requests, reconsiderations, and appeals;
- Ensure that each level of appeal and reconsideration is a meaningful opportunity for the clinician and patient to demonstrate medical necessity. Clinicians and patients should not have to move through layers of process that repeatedly apply the plan's policies in the same manner as the original denial; and
- Reiterate and enforce the MA requirement that plans not restrict coverage for products and services covered in traditional Medicare.

These recommendations should lead to more transparent and consistent utilization-management processes. This will reduce the amount of time and resources providers and patients spend navigating the process and promote quicker patient access to needed therapies.

Clarifying Use of Advance Beneficiary Notice of Noncoverage

Although clinicians submitting claims for Part B services under traditional Medicare do not have to navigate a prior-authorization process to obtain coverage approval, access hurdles related to clinician coverage uncertainty can present a near-absolute impediment for patients, particularly for higher-cost treatments. The Advance Beneficiary Notice of Noncoverage (ABN) transfers potential financial liability to the Medicare beneficiary. Although its use is ostensibly limited to situations where Medicare payment is expected to be denied, it is also being used in when clinicians are not certain of coverage and wish to transfer liability.

We believe that CMS instructions on use of the ABN are subject to conflicting interpretation. For example, under §1879 of the Social Security Act, a provider should notify a beneficiary in advance when s/he believes items or services **will likely be denied** either as not reasonable and necessary or as constituting custodial care. The ABN Quick Glance Guide, however, states that providers should present the ABN “prior to providing an item or service that is usually paid for by Medicare . . . **but may not be paid** for in this particular case because it is not considered medically necessary.”⁵ The NHC is concerned that the grey area between services that are likely to be denied and those that merely may be denied creates variability based on the provider's risk perception and tolerance. Beneficiaries have no recourse to appeal if a provider requires transfer of financial liability before treating the patient. We urge CMS to either provide further guidance to clinicians or consider implementing a process through which

⁵ <https://www.cms.gov/Medicare/Medicare-General-Information/BNI/Downloads/ABN-CMS-Manual-Instructions.pdf>

beneficiaries and providers can secure a clarification on coverage before transferring financial liability to the patient.

Quality reporting requirements

The NHC has previously commented on CMS' implementation of the Quality Payment Program (QPP) and believes that quality measures can help payers reward better care, inform providers on when they need to take action to improve care, and enable patients to make better-informed decisions about where to seek care. Although the information collected through the QPP on objectively measurable outcomes and processes can be helpful in ensuring that care for complex patients is delivered within clinical guidelines, it gives little insight on quality from the patient perspective.

We urge CMS to look at simple solutions that might make QPP reporting processes more streamlined for providers and to work with stakeholders to identify measures that are more directed toward outcomes patients care most about. CMS could, for example, build on the outreach activities associated with the Patients over Paperwork initiative to better engage patients in the development of quality measures that are patient centric.

Information Request: Enabling of operational flexibility, feedback mechanisms, and data sharing that would enhance patient care, support the clinician-patient relationship, and facilitate individual preferences.

The NHC believes that the best way to support the clinician-patient relationship and facilitate patient preferences is to incentivize treatment planning and shared decision-making throughout the patient journey. This means clinicians should be encouraged to provide covered treatment-planning services when they can be most useful, including when a new diagnosis is received, a new medication is given, or the patient experiences life changes that might impact their care and goals.

We also note that CMS has recently initiated policies to improve transparency for patients within the context of an office visit, including increased and readily available information on the cost of a prescribed treatment, patient cost-sharing burden, and identification of any alternative treatments that are less costly. The NHC agrees that informed patients are better able to make health care decisions that are consistent with their needs and goals. We believe, however, that information must be meaningful, understandable, and related to the patient's treatment needs and urge CMS to engage stakeholders to develop language on drug cost, price increases, and cost-sharing that is clear, consistent, understandable, and related to beneficiaries' out-of-pocket costs. Medicare beneficiaries with chronic diseases and disabilities depend on their medicines to manage their conditions and can be inundated with layers of information from various sources with little guidance on how to sort through it, much less how to incorporate it into medical decisions. Thus, it is imperative that we avoid an unintended consequence of creating a burdensome process that only layers on information that is unusable to patients.

We also urge CMS to consider other means of communications that may be more meaningful and actionable. For example, including information about out-of-pocket costs and utilization management tools in the Medicare Plan Finder would help seniors choose a plan that best meets their needs. Medicare beneficiaries should also know, in advance of enrolling, whether an MA plan uses step-therapy protocols for Part B drugs and be able to discuss that with their clinician and understand what impact it may have on access to treatments they are using, have successfully used in the past, or have a likelihood of needing in the near term.

Information Request: New recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, and providers.

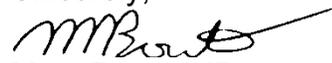
The NHC understands that CMS seeks to balance the public interest in ensuring stakeholders have a meaningful opportunity to inform important policy changes with the Agency's interest in streamlining implementation of refinements that might improve the quality of care, reduce burden for patients and providers, and/or result in cost savings. We urge CMS to take a conservative approach in favor of stakeholder engagement and limit its use of sub-regulatory guidance to minor refinements that are unlikely to have substantial impact on beneficiaries. Whenever a change, refinement, or clarification of existing policy has potential to impact patient rights, the care patients receive, or how much they pay, we urge CMS to provide proper notice and opportunity for comment.

We also urge CMS to ensure the patient and caregiver communities have sufficient time to review policy changes, assess potential impact, and submit comments. Thirty or fewer days between Federal Register publication and the comment deadline is too short for meaningful feedback, particularly from the patient community.

Conclusion

We thank CMS for the opportunity to respond to the RFI and applaud its efforts to increase the level and quality of patient engagement informing program changes and refinements. Please do not hesitate to contact Eric Gascho, Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,



Marc Boutin, JD
Chief Executive Officer
National Health Council