January 4, 2021

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications (CMS-9123-P)

Dear Administrator Verma,

The National Organization for Rare Disorders (NORD) appreciates the opportunity to submit comments on the proposed rule captioned above. NORD is a unique federation of voluntary health organizations dedicated to helping the 25-30 million Americans living with a rare disease. We believe that all patients should have access to quality, accessible and affordable health coverage that is best suited to their medical needs.

While 90% of rare diseases have no U.S. Food and Drug Administration (FDA)-approved treatment, some rare disease patients are fortunate to have an FDA-approved medication intended to treat their rare disorder or other co-morbidities. However, the administrative burden often associated with prior authorization protocols can make timely access to these treatments a challenge. NORD applauds the Centers for Medicare & Medicaid Services (CMS)for taking steps to improve the electronic exchange of health care data and reduce the patient and provider burdens related to prior authorization requirements. However, given the complex nature of the changes involved within this proposed rule, CMS should extend the comment period to allow all stakeholders to provide robust comments.

Our initial comments on specific provisions of the proposed rule are included below.

Streamlining the Prior Authorization Processes
Utilization management protocols, such as prior authorization, are important tools that can help control costs and prevent the overuse of health care services. However, when used improperly or without consideration of a patient's unique medical situation or history, utilization management protocols can delay necessary treatment by weeks or even months. Particularly for patients with rare diseases, delayed access to treatment can lead to medical setbacks, disease progression, loss of function, and even hospitalizations. For these reasons, NORD is supportive of the polices

within this proposed rule that are designed to improve the efficiency and transparency of prior authorization protocols.

If implemented, this proposed rule would require payers to maintain interoperable application programming interfaces (APIs) that would allow providers to know in advance the documentation needed for a prior authorization application, and to submit prior authorization requests and receive responses electronically. Payers would also be required to list the items and services requiring prior authorization and associated documentation requirements on a public-facing website. In addition, the proposed rule would require that payers provide a specific reason for denying a prior authorization request, and to send prior authorization decisions within 72 hours for urgent requests and seven calendar days for standard requests.

NORD believes that these proposals would reduce delays to care that are solely the result of burdensome administrative protocols. However, we are concerned by the omission of outpatient prescription drugs from this proposed rule. Many patients living with rare diseases depend on access to outpatient prescription drugs and/or biologics for the treatment and management of their condition. If this rule is finalized as written, these patients will continue to experience unnecessary delays in accessing their therapies. While NORD supports the provisions within this proposed rule regarding prior authorization, we encourage CMS to expand the rule to encompass outpatient drugs.

Although NORD supports the intent of this proposal, NORD is concerned that the operational aspects will pose significant challenges for state Medicaid programs. Successfully implementing the provisions of this proposed rule will require substantial state resources, at a time when many states are facing significant budget cuts due to the financial crisis caused by COVID-19. Therefore, we encourage CMS to provide enhanced technical and financial support for state Medicaid programs to assist states with the development and maintenance of new provider APIs to enable Medicaid beneficiaries to fully benefit from the reforms outlined within this proposed rule.

Request for Information on Repeated Prior Authorization for Chronic Conditions
NORD is supportive of policies that could improve the continuity of care for patients with rare diseases. Repeated reauthorizations for items and services inserts uncertainty into a patient's treatment plan and puts unnecessarily burdens on both patients and providers. Plans regularly have varying timelines for reauthorization, and some plans may require that items and services be reauthorized as often as every 3 or 6 months. These short timelines do not align with clinical practice and may lead to disruptions in care. For patients with rare or chronic conditions, we urge CMS to institute a minimum 12-month standard for all reauthorizations to limit disruptions to care and reduce provider burden.

However, it is essential that eligibility for long-term authorizations are not restricted to a list of pre-determined conditions. On average, it takes more than 5 years for a patient with a rare

disorder to receive an accurate diagnosis and effective treatment.[1] Further, only a handful of the 7,000 known rare diseases are well understood, with most not receiving sufficient attention or funding for research. Should prior authorization exemptions or a long-term authorization be tied to specific conditions, there is a high likelihood that patients who-have-yet-to-be-diagnosed, or are living with a known rare condition, will be overlooked. CMS should instead create a process through which a patient's health care provider may attest that their condition is chronic and therefore enable access to an exemption or long-term authorization process.

Request for Information on Portability of Prior Authorization Approvals

NORD encourages CMS to explore options to improve the portability of prior authorization between payers. In some cases, patients who move from one payer to another may be required to stop taking a successful treatment and start taking a medicine that they have already failed on simply because the prior authorization protocol does not take into account whether a patient has failed a medicine while covered by another insurer. Patient protections that improve plan-to-plan portability are especially important for Medicaid beneficiaries, where "churn" between payers is reported to be as high as 30%.[2]

NORD urges CMS to require that payers honor the prior authorization granted to an enrollee from a previous utilization review entity for *at least* the initial 60 days of an enrollee's coverage under a new health plan. NORD also encourages CMS to explore additional polices to protect patients from disruption of care as they move between payers. Regarding step therapy protocols, numerous states have implemented laws that require an exemption be granted from a payer's step therapy protocol if a patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. NORD supports efforts to allow prior authorization approvals to move with patients between health insurers or health benefit plans for longer than 60 days when the patient is considered stable and the prescribed treatment is deemed by their health care provider to be medically necessary.

Exclusion of Medicare Advantage & Qualified Health Plans

NORD believes that this proposed rule could substantially improve timely access to health care for patients with rare diseases. However, we disagree with CMS' decision to exempt Qualified Health Plans (QHPs) from several major provisions of this proposed rule, including the proposed timelines for prior authorization approvals. This would withhold the benefits of streamlined prior authorizations from the millions of patients who are enrolled in plans through the federally facilitated exchanges.

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[1] Engel PA, Bagal S, Broback M, Boice N. Physician and patient perceptions regarding physician training in rare diseases: The need for stronger educational initiatives for physicians. *J Rare Dis*. 2013;1:1-15.

[2] Roberts, Eric T, and Craig Evan Pollack. "Does Churning in Medicaid Affect Health Care Use?." *Medical care* vol. 54,5 (2016): 483-9. doi:10.1097/MLR.0000000000000509.

Likewise, we urge CMS to extend this rule to Medicare Advantage (MA) plans. We are concerned that if finalized this exclusion would create misalignments between Medicaid and Medicare that could affect dually eligible individuals enrolled in both a Medicaid managed care plan and an MA plan.

Conclusion

NORD applauds the goals of this proposed rule and looks forward to continuing to work with CMS to ensure that all rare disease patients have timely access to essential, high-quality health care. Therefore, NORD urges CMS to require QHPs and MA plans fully comply with the prior authorization reforms proposed within this rule. Additionally, we strongly urge CMS to include additional technical and financial support to state Medicaid programs to implement the proposed APIs and expand the rule to include reforms to prior authorization requirements for outpatient prescription drugs and/or biologics. NORD also urges CMS to extend the comment period to permit stakeholders an opportunity to conduct a more thorough analysis of these proposals.

NORD thanks CMS for the opportunity to submit comments. For questions regarding NORD or these comments, please contact Corinne Alberts at calberts@rarediseases.org.

Sincerely,

Heidi Ross
Director of Policy