February 19, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9926-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CMS-9926-P Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020

Dear Administrator Verma:

On behalf of the 30 million Americans with one of the approximately 7,000 known rare diseases, the National Organization for Rare Disorders (NORD) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments on the agency's proposed rule entitled, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020."

NORD is a unique federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services.

NORD is supportive of efforts to enhance and strengthen the Affordable Care Act's (ACA) insurance reforms that provide critical protections for rare disease patients. We support the Administration's proposed additional special enrollment period and the proposed changes to the permanent risk adjustment program as both should strengthen the insurance market and expand access to quality insurance offerings.

However, the Administration's proposed changes to the premium adjustment factor formula, the maximum out-of-pocket (MOOP) limit, the navigator and broker programs, cost-sharing requirements and drug manufacturer coupon calculations, and the essential health benefits, among others, may weaken access to quality, affordable coverage for rare disease patients. We strongly encourage the Administration to reconsider these changes before finalizing this proposal.

Automatic Re-Enrollment

CMS has sought comment on possibly changing the process for automatically re-enrolling consumers in health insurance plans offered through a Federally-facilitated Exchange (FFE) or State-based Exchange (SBE). Currently, consumers are automatically re-enrolled in their current plan if they do not take action

to change their plan. In 2018, approximately 25 percent of consumers were automatically renewed in their plan;[1] a total of 1.8 million were re-enrolled for plan year 2019.

NORD supports the current system of automatic re-enrollment and is concerned that a significant number of rare disease patients would be unwittingly left uninsured or with gaps in coverage if it were removed. This would be a particular concern for our population as individuals with rare diseases require specialized health coverage. Given the lack of a compelling reason to change the policy, we urge CMS to retain auto-renewal in its current form.

Mid-Year Formulary Changes (45 C.F.R. § 156.122)

In the proposed rule, CMS reaffirms its interpretation of the federal guaranteed renewability requirement that requires health insurance issuers to modify their coverage only at renewal and, therefore, generally prohibits issuers from removing a drug from the formulary or changing its tier in the middle of a policy year. NORD is supportive of this policy clarification as it avoids patient confusion in the middle of the benefit year and ensures uninterrupted access to often lifesaving therapies for rare disease patients.

NORD, however, opposes a blanket exception for generic equivalent drugs, given that generic equivalent drugs may be unaffordable for a patient. Coupled with CMS' proposed policy of allowing insurers to refrain from applying manufacturer copay assistance to annual limits on cost sharing when there is a generic equivalent, this exception could result in patients being forced, in the middle of a plan year, to forgo a brand drug for which they had financial assistance and instead take a new generic drug with no similar cost assistance. If beneficiaries have yet to meet their deductible, they could face hundreds of dollars in unanticipated out-of-pocket costs before experiencing the potentially lower cost-sharing requirements of a lower generic tier.

Of additional concern, the proposed rule does not define the term "generic equivalent." NORD encourages CMS to clarify that the term "generic equivalent" means a generic drug that the Food and Drug Administration (FDA) has determined to be "therapeutically equivalent" to the brand, i.e. AB-rated in FDA's Orange Book. Further, we encourage CMS to clarify whether "generic equivalent" includes biosimilars and, if so, whether these biosimilars must be interchangeable, highly similar, or some other measure of equivalence.

Risk Adjustment (45 C.F.R. § 153.350(c) & 45 C.F.R. § 164.514(e))

The permanent risk adjustment program plays an integral role in promoting insurance quality by minimizing risk selection and encouraging insurers to develop insurance products that are competitive in price and value. An accurate and effective risk adjustment program is essential in preventing discriminatory insurance benefit designs and protecting access to care for patients with rare diseases.

Given the importance of the permanent risk adjustment program in protecting consumers and transferring billions of dollars among participating plans, we support CMS' proposal to improve the

[1] Armour S. Trump's Proposed ACA Rules Could Boost Costs for Millions of People. The Wall Street Journal. 2019. https://www.wsj.com/articles/trumps-proposed-aca-rules-could-lift-costs-for-millions-of-people-11547775475?emailToken=774bc4bebc0f134eb1cbdb62929ce275slrMAjxYosOIBrHl2PV0GhknF/RER9kfvVE2/R4Uup5GtaR04vGLsQ+2sU34h6a/7caWwpP7v/ncdNJP4A8l8U8HSz7rRRnF/utKpV9ZDyiA8UuvgT0Dvn3OvxPwA8JL&reflink=article_email_share.

program's methodology by adding prescription drugs into error estimations. As CMS recognizes, "The incorporation of prescription drug data helps reduce incentives for issuers to avoid making available treatments for high-cost conditions in their formularies, and can effectively indicate health risk in cases where diagnoses may be missing."

This revision is particularly important for the rare disease patient community as prescription therapies for rare diseases (orphan drugs) are more likely to be particularly expensive. In addition, there are many Americans with undiagnosed conditions that would benefit from this proposed change. The newly proposed risk adjustment program methodology should prevent plans from designing benefit packages that select against rare and undiagnosed patients who rely on prescription drugs.

In addition, we support CMS' proposal to release data related to the risk adjustment program for research and public health purposes. A program as important as risk adjustment will benefit from the opportunity for external accountability that comes with providing researchers outside the government with these data.

Premium Adjustment Factor (§ 153.320)

In the proposed rule, CMS proposes changing the premium adjustment factor formula for calculating changes to subsidies, out-of-pocket caps, and other costs. While CMS previously calculated the premium adjustment factor based on employer-sponsored insurance premiums, CMS would now use average private health insurance premiums in the formula— raising the premium adjustment factor by 3.6 percent from 2019. Should this proposal be finalized as drafted, CMS anticipates that premiums for approximately 7.3 million subsidy-eligible individuals and families could increase by up to $220, resulting in approximately 100,000 consumers losing their health insurance coverage in 2020 alone.

The proposed change to the premium measure will also result in a faster growth of the net premiums paid by consumers on the Exchange and a faster growth in the maximum out-of-pocket (MOOP) limit paid by all Americans, including those with large group employer coverage.

While most of the 100,000 consumers who could lose coverage are expected to remain uninsured, some may purchase short-term, limited-duration health plans (STLDHPs or short-term plans). STLDHPs do not provide adequate coverage and will expose consumers to medical debt, scams, and harm to both their short- and long-term health. Further, consumers who remain uninsured and underinsured will likely delay needed care, resulting in worse health outcomes and potentially increasing uncompensated care costs.

We are concerned that the proposal will lead to higher costs that will result in rare disease patients forgoing medically necessary services. This in turn will lead to worse health outcomes and more uncompensated care from patients accessing emergency services. Studies show that a growing number of Americans are underinsured and, therefore, experience difficulty paying the out-of-pocket costs associated with their care, including deductibles, copays, and coinsurance.

This holds true for a cross-section of Americans (including those with large group employer coverage as well as those with individual coverage)— but it is an especially pressing concern for people with rare

diseases. These increased costs will disproportionately impact rare disease patients and do not reflect out-of-pocket costs for non-covered services.

Finally, NORD is concerned about the compounding effect of using the alternative premium measure beyond the 2020 plan year. The changes put forward in the proposed rule, if finalized, would erode the premium tax credits, making them less impactful for low to middle income Exchange consumers. This will result in an estimated 100,000 individuals annually losing their health coverage. Further, the MOOP limit would grow at a faster rate, leaving every American with private insurance increasingly vulnerable to higher out-of-pocket costs.

We are alarmed at the hypothesis found in the preamble stating that "[e]conomic distortions may be reduced, and economic efficiency and social benefits improved, because these individuals will be bearing a larger share of the costs of their own health care consumption, potentially reducing spending on health care services that are personally only marginally valued but that imposes costs on the federal government through subsidies." A recent study assessing consumer responses to high deductible health plans aligns with other well-documented data showing that patients faced with high out-of-pocket costs forgo valuable care at the same rate as unnecessary care.

These high out-of-pocket costs include high deductibles, high patient cost-sharing capped by the MOOP limit, payments for uncovered services, and even the full cost of health care borne by those without insurance. Therefore, while we applaud the Administration's efforts to reduce the cost of care, we urge the Administration to withdraw proposals that would increase the rates of uninsured and reduce coverage and instead to work with us to put forth options that ensure adequate coverage and improve value.

NORD opposes this unnecessary change to existing policy and urges the Administration to withdraw these changes to the premium adjustment formula. We also request that the Administration not take any additional actions that would further increase premiums and out-of-pocket costs for consumers as such changes are likely to increase the number of people that forgo insurance or purchase inadequate coverage.

Navigators & Web Brokers (45 C.F.R. § 155.210(e), 45 C.F.R. § 155.210(b), & 45 C.F.R. § 155.220)

Under the Affordable Care Act (ACA), Navigators assist consumers by providing information regarding enrollment in Qualified Health Plans (QHPs) as well as post-enrollment activities, such as increasing health literacy, assisting with renewals, and educating consumers on how to avoid disenrollment for non-payment. The proposed rule would make these important post-enrollment activities optional for Navigator programs in an effort to increase flexibility for FFE Navigators. FFE Navigators would also no longer have to receive training on 20 currently required training topics.

While Navigators are currently assuming a significant role, NORD believes the solution should be to restore funding for this important role, rather than to further limit services for rare disease patients seeking assistance. We have communicated with the Administration about the vital role Navigators play in today's health care marketplace and are concerned that the proposal further erodes their ability to assist rare disease patients with enrolling in comprehensive coverage, including Medicare and Medicaid,

that meets their individual medical needs. We oppose the proposed changes to the Navigator program and urge the Administration to restore funding for this important resource.

We are also concerned that the proposed rule would allow "web brokers" to facilitate Exchange enrollment through the websites of third-party "direct enrollment entities," including issuers. These new proposals would shift focus away from healthcare.gov and increase the likelihood that web-brokers could recommend plans to rare disease patients, including plans with less than adequate coverage, such as short-term or association health plans, while failing to provide the useful information consumers need to make informed choices. As a result of these concerns, we oppose this change and urge the administration to remove it from the final rule.

Direct Enrollment (45 C.F.R. § 155.20, 45 C.F.R. § 155.210, & 45 C.F.R. § 155.221)

Currently, the Exchanges rely on healthcare.gov to enroll rare disease patients into health insurance plans. Healthcare.gov has specific safeguards built into the system to help ensure that consumers choose a plan that is the best option for them. The Exchange also identifies consumers who are eligible for Medicaid or Medicare. This is a key feature of the Exchange, allowing consumers to enroll in the most affordable and medically-appropriate plan.

The Exchange also calculates a patient's advanced premium tax credit (APTC) and eligibility for a cost-sharing reduction (CSR) silver plan. These features allow consumers to accurately compare the cost of the premiums between different plans and metal levels. By knowing the value of the APTC, consumers can purchase the plan that has the most value for them and their health care needs.

In the proposed rule, CMS proposes expanding direct enrollment, which would allow insurers and web-brokers to enroll consumers in an insurance plan directly. Allowing these entities to directly enroll consumers in plans will limit the ability to compare plan price and benefit design and could ultimately result in harm to consumers who become enrolled in inadequate insurance coverage. This failure to appropriately shield rare disease patients from risk is unacceptable. As such, we urge CMS to not finalize this provision of the proposed rule.

Changes to direct enrollment under this proposal would also not require an insurer or web-broker to list out all the plans available to a consumer shopping for health insurance. The proposed rule would only require the insurer or web-broker to link to other plans or add a disclaimer that other plans are available at healthcare.gov. Brokers frequently receive bonuses from insurers for signing consumers up for certain plans, creating an incentive for brokers to enroll individuals in plans that may not be the best option for them.

Encouraging direct enrollment will also expose rare disease patients to plans that are not qualified health plans (QHPs) during enrollment— including substandard options, such as short-term and association health plans. Currently, every plan sold on the Exchange is a QHP, meaning it covers the ten essential health benefits (EHB), including emergency room services, physician services, and prescription drugs. Today, rare disease patients can trust that they are purchasing a health insurance plan that will cover all that is necessary to manage their health condition. Insurers and web-brokers selling both QHP plans and non-QHP plans may steer consumers into less comprehensive, less expensive plans. This is particularly

concerning for those in the rare disease community as they often require highly-specific and comprehensive coverage for rare, often misunderstood, conditions.

Non-comprehensive, skimpy health plans do not cover the services and treatments our patients need to manage their diseases and, in many cases, stay alive. Any confusion caused by obscuring the information rare disease patients need to make informed health care decisions can result in our patients not getting the care they need. We strongly urge CMS to not adopt this provision in the final rule.

Special Enrollment Periods (45 C.F.R. § 155.420)

Special enrollment periods (SEPs) provide an important opportunity to enroll in coverage when consumers' circumstances change during the course of the year. We support CMS' proposal to establish a special enrollment period for individuals with off-Exchange coverage who experience mid-year income changes to facilitate consumer access to more affordable Exchange plans when they become eligible for advance payments of the premium tax credits.

Given that this SEP may be implemented at the discretion of state-based Exchanges, we strongly encourage CMS to consider requiring state-based Exchanges to establish an SEP for individuals with off-Exchange coverage who experience mid-year income reductions as well.

Silver Loading

In October of 2017, the Administration, per advice from the Attorney General, stopped funding the cost-sharing reduction payments (CSRs) that section 1402 of the ACA requires insurance companies provide to low-income Exchange enrollees. As issuers were still required to provide the subsidies to low-income enrollees but no longer received federal funding to pay for them, they increased premiums to cover their costs. The practice of silver loading refers to increasing premiums only for on-Exchange silver plans to cover the cost of CSRs, as opposed to spreading the cost over all individual Exchange plans.

An unexpected but beneficial result of silver loading for rare disease patients has been an increase in the value of advanced premium tax credits (APTC), since the government calculates APTCs using the cost of the second-lowest cost Exchange silver plan. This has made it possible for some consumers to pay less for bronze or gold plans than they would have otherwise.

It is important that CMS allow silver loading to continue until such time as a broader solution on CSR payments, stabilization, and marketplace affordability is reached. Absent silver loading, premiums for all individual market plans will rise and the value of APTCs will fall, exacerbating affordability issues for unsubsidized and subsidized rare disease patients alike.[2] NORD supported marketplace stabilization efforts in the last Congress and will continue to call for renewed efforts on this topic.

Until there is a permanent solution regarding the CSR payments and the overarching affordability of insurance premiums, we urge CMS to continue to allow silver loading. By staying consistent and keeping silver loading, the market will be more stable. A stable market and insurance premiums that reflect market stability are important for rare disease patients. Patients need to be able to plan health care

[2] Anderson D. et al. Implications of CMS Mandating A Broad Load Of CSR Costs. Accessed February 7, 2019. https://www.healthaffairs.org/do/10.1377/hblog20180511.621080/full/.

costs more than 12 months into the future. Most rare disease patients will need treatment for the rest of their lives. It is important that they can plan for their future.

Only when permanent and stable CSR funding is secured should silver loading be disallowed. If or when this occurs, some patients could experience increased out-of-pocket costs for premiums as a result of the less generous APTCs. In this situation, we would encourage CMS to phase out silver loading gradually to lessen the financial impact on patients and keep stability in the marketplace.

Finally, while we acknowledge that silver loading has negative impacts on consumers who do not qualify for APTCs and desire to purchase more expensive silver plans, the benefits to those who are able to afford insurance due to silver loading are far too substantial to lose.

Essential Health Benefits (EHBs) (45 C.F.R. § 156.111, 45 C.F.R. § 156.115 & 45 C.F.R. § 156.122)

NORD remains concerned with proposals finalized by CMS in the Notice of Benefit and Payment Parameters for 2019 that weakened the EHBs. Last year, the Administration allowed states to choose EHB-benchmark plans from other states as well as choose specific EHB categories from other states. We strongly opposed this proposal as we envisioned that it could lead to a "race to the bottom" consisting of states choosing to implement inadequate coverage standards from other states.

We once again strongly urge CMS to withdraw this allowance. While only one state, Illinois, chose to utilize these new options and the outcome was positive, we remain concerned that other states may choose to design new EHB-benchmark plans that would not provide adequate benefits for rare disease patients.

We are also concerned that the flexibility allowed under this policy, combined with other administrative actions finalized by the Administration, such as the expansion of AHPs and short-term plans and the new guidance on 1332 waivers, could allow states to degrade patient protections and could give them the authority to offer not just less generous coverage, but the least generous coverage possible under law.

Further, regarding prescription drug benefits, NORD is concerned that therapeutic substitution could result in serious harm to some within the rare disease community. Changes to a patient's therapeutic regimen can be devasting. Particularly as we remain unconvinced that therapeutic substitution could substantially lower health care costs, we do not believe that an attempt at its implementation is worth the risk to patients.

Finally, CMS has requested stakeholder feedback on potentially requiring reference pricing for prescription drugs in Exchange plans. While we support the Administration's goals of lowering the costs of care for rare disease patients by bringing down the costs of prescription drugs, we urge CME to proceed with caution.

As explained in our December 31 comments on reference pricing in the Medicare Part B program:

> We are concerned…that substantially altering the reimbursement for these therapies has the potential to unduly hurt innovation and limit access. Further, we are concerned that the addition

of this restriction could potentially disincentivize manufacturers from offering their therapies within Medicare Part B or, conversely, incentivize them to increase their prices in the private sector to compensate for their loss. Were any of these scenarios to become reality, rare disease patients, not the Federal Government, would be harmed.[3]

We have similar concerns regarding the implementation of referencing pricing within Exchange plans without proper precautions.

Maximum Annual Limitation on Cost Sharing for Plan Year 2020 (45 C.F.R. § 156.130)

NORD opposes CMS' proposal to increase the maximum out-of-pocket (MOOP) limit to $8,200 for an individual plan and $16,400 for a family plan. Rare disease patients often require costly and extensive care, including prescription drugs, emergency services, various physicians and specialists, and more. Consequently, the cost of caring for a rare condition can be much more expensive than for other conditions.

The increase in the MOOP will disproportionately harm those in the rare disease community as they are much more likely to reach the increased limit and, therefore, would incur the additional out-of-pocket costs not incurred in 2019. We urge CMS to reconsider raising the MOOP.

Brand Drugs and Essential Health Benefits (45 C.F.R. § 156.130)

We strongly oppose CMS' proposal to only count generic drugs within EHBs, which would result in only the cost of generics, not brand drugs, counting towards a patient's MOOP limit. As discussed previously, generics for orphan therapies may not be much more affordable than the reference product. Studies have shown that the prices of generics do not significantly differ from the reference product until there are two or more generics on the market.[4] Of the small percentage of orphan indications with a generic or biosimilar, an even smaller percentage have more than one generic on the market. If patients were to stay on a brand drug for the sake of acquiring financial assistance, we would hope that their payments could still count toward their MOOP.

We ask that CMS remove this proposed change prior to finalizing the rule. If, however, CMS moves forward with this proposal, we ask that CMS consider ways to allow the brand drug to be included in all EHB packages and, therefore, apply toward a patient's MOOP for all scenarios in which the existing generic is no more affordable than the brand.

Cost-Sharing Requirements and Drug Manufacturers' Coupons (45 C.F.R. § 156.130)

In the midst of rising drug prices, a dramatic increase in the number of high-cost, specialty pharmaceutical products, and ongoing efforts by payors to develop formulary benefit designs that drive patients toward lower-cost choices, NORD remains deeply troubled by policies that ultimately increase

[3] "Policy Statements." National Organization for Rare Disorders. December 31, 2018. Accessed February 19, 2019. https://rarediseases.org/wp-content/uploads/2019/01/NORD-2018-Comments-on-CMS-IPI-ANPRM.pdf.
[4] Center for Devices and Radiological Health. "About the Center for Drug Evaluation and Research - Generic Competition and Drug Prices." US Food and Drug Administration. Accessed February 19, 2019. https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

the burden on patients in an attempt to achieve reform. Thoughtful debate and policymaking should occur with regard to drug pricing in America today, but it should not come at the expense of patients and their families who are trying to access lifesaving medications today.

For these reasons, we are concerned by CMS' proposal to not count assistance offered by drug manufacturers to insured patients to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have a generic equivalent toward the annual limitation on cost sharing. NORD believes such a policy is misguided.

In the proposed rule, CMS notes that "manufacturer coupons may be increasing overall drug costs and can lead to unnecessary spending by issuers." In response, CMS is proposing to exclude cost sharing paid by a manufacturer coupon for a brand drug from the plan's annual limitation on cost sharing when a health plan covers both the brand drug and the generic equivalent for the brand.

NORD recognizes that the high cost of drugs has a direct impact on patient access. Addressing this and other barriers to care is a priority for NORD. Further, NORD acknowledges the immense pressure that payors are under to control costs for the sake of all beneficiaries. Yet, as noted above, we do not believe that attempts to redress rising costs should come at the detriment of patients. Failing to support patients today, who are in need of immediate assistance to pay for their prescribed treatment, will have a devastating impact on their health.

Cost is a primary reason for patients declining to fill their prescriptions.[5] Further, non-adherence to prescribed medication is responsible for an estimated 125,000 deaths, ten percent of hospitalizations, and hundreds of billions of dollars in costs to the health care system per year.[6][7]

With this in mind, it is critical that payments made by patients, or on behalf of patients, apply toward their annual limitation on cost sharing. Without applying payments in this manner, patients will be less likely to meet their deductible and, thus, may quickly exhaust any assistance they may have by repeatedly paying for the full cost of the drug. If that happens, patients will be left having to pay the bulk of their deductible as well as the entirety of their copay or coinsurance, despite having already spent enough to meet their deductible, and could be forced to decide between forgoing their critical therapy or facing medical bankruptcy.

Furthermore, with regard to the specific policy in the proposed rule, NORD has several additional concerns. First, the proposal would seemingly apply in the case of any branded drug with a generic equivalent, even if there is only a single generic equivalent available on the market and the price of the generic equivalent is the same as the price of the branded product. As we have stated, such a policy could force patients, including rare disease patients, to forgo needed medication due to high costs.

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[5] Health Poll: Prescription Drugs. Report. NPR, Truven Health Analytics. 2017. Accessed February 6, 2019. http://truvenhealth.com/Portals/0/Assets/TRU_18156_0617_NPR_Poll_Prescription_Drugs_FINAL.pdf

[6] Viswanathan M, Golin CE, Jones CD, Ashok M, Blalock SJ, Wines RC, et al. Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review. Ann Intern Med. ;157:785–795. doi: 10.7326/0003-4819-157-11-201212040-00538

[7] Brody, Jane E. "The Cost of Not Taking Your Medicine." The New York Times, April 17, 2017. Accessed February 6, 2019. https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html?login=email&auth=login-email.

Again, CMS could potentially mitigate such an impact by taking a more nuanced approach and implementing a policy that would take into account the possibility of prohibitively expensive generic equivalents. NORD would be happy to work with CMS to identify an approach that would only allow plans to exclude cost-sharing support for brand drugs with a generic equivalent on formulary from the annual limitation on cost sharing in specific situations. Absent such nuance, rare disease patients and their families could face severe access issues.

Second, the proposed rule is silent as to the ability of plans and issuers to prohibit the application of assistance in cases where there is not a generic equivalent version of that same drug on the plan's formulary. While it is possible that CMS' intent is to require that a plan or issuer count the value of such support, we are concerned that absent further clarification, plans and issuers could misconstrue or misinterpret the lack of clarity to the detriment of rare disease patients, if the rule is finalized as proposed.

Finally, as mentioned above, the proposed rule could benefit from additional clarity around the term "generic equivalent." As it stands, it is unclear what this term means and what it could potentially encompass.

We encourage CMS to retract its proposal on manufacturer cost-sharing assistance given its detrimental impact on patient access. If CMS still desires to proceed with a variation of the rule, we hope that it will work with stakeholders to develop a nuanced approach that will not hamper access to needed medications. Finally, we urge CMS to clarify that cost-sharing support for a brand drug on the formulary should always count toward the annual limitation on cost sharing if there is no AB-rated generic for that specific drug available on the formulary.

We thank CMS for the opportunity to comment and look forward to working with CMS on improving access to quality, affordable health coverage for the approximately 30 million Americans with a rare disease. For questions regarding NORD or the above comments, please contact me at pmelmeyer@rarediseases.org, or 202-545-3828.

Thank you in advance for your consideration of these comments.

Sincerely,

Paul Melmeyer
Director of Federal Policy