July 25, 2021

Dear CCIIO Colleagues,

On behalf of the Chronic Illness and Disability Partnership (CIDP), we would like to thank you for meeting with our groups on June 28th. Our organizations represent health care consumers with a range of chronic conditions and disabilities, including cancer, multiple sclerosis, HIV, and mental health and substance use conditions. We appreciate the work that CCIIO has done to ensure that vulnerable communities with more intensive healthcare needs have access to affordable and meaningful coverage through ACA-regulated insurance products.

We believe there are opportunities that CCIIO has via the Notice of Benefit and Payment Parameters for 2023 regulatory process as well as direct agency action to better protect these communities and hope you will consider the following recommendations:

PRESCRIPTION DRUG COVERAGE
Access to affordable prescription drugs that meets standards of clinical care is critical to the health of consumers living with chronic conditions and disabilities. The protections the Affordable Care Act (ACA) provides against discriminatory plan design and transparency have been important to our communities, but more must be done to ensure that vulnerable consumers have meaningful access to care and treatment.

- *Minimum prescription drug coverage standards should be increased*
  CMS should amend 45 CFR §156.122(a)(i) to increase the EHB floor for prescription drug coverage standard from one drug per U.S. Pharmacopeia drug category/class to two, in line with current Medicare Part D standards. Though plans must cover the greater of the one drug per category/class standard or the number of drugs per category/class in the state's benchmark plans, we believe increasing the floor is important, particularly as plans take on increasingly drastic prescription drug cost cutting measures.

- *More restrictive mid-year formulary changes must be prohibited*
  There are countless examples of consumers with a cancer or HIV diagnosis who choose a plan based on the formulary design and coverage, only to have their issuer make a more restrictive mid-year change to the formulary that excludes a needed medication or places the medication on a higher cost-sharing tier. We urge CMS to amend 45 CFR §147.106 to include a new subsection explicitly prohibiting *adverse* mid-year formulary changes. While short of a full solution to the problem of mid-year formulary changes, in the alternative as an interim step, CMS should bolster the notice requirements for plans

that make changes to their formularies mid-year, requiring that the plan not only notify consumers about the formulary change, but also provide information about how consumers can access non-formulary drugs via the exceptions process.

- *Formulary transparency requirements must include drugs covered under a medical benefit and prohibit plans from counting drugs only available through an exceptions process a part of a formulary*
  Consumers are not able to make informed choices about plans unless they know what is covered. This is particularly true for consumers living with chronic conditions for whom medication coverage is often one of the biggest factors in plan choice. Many consumers across chronic conditions are prescribed injectable or physician-administered medications, however these drugs are often not included on publicly available plan formularies because they are categorized as part of a medical benefit instead of a pharmacy benefit. Similarly, plans are also categorizing drugs that are only available via an exceptions process as part of their formulary, creating a bait and switch for consumers when they try to access the medication. We urge CCIIO to amend 45 CFR §156.122 to require issuers to include information about drugs covered as a medical benefit on their formularies, or easily link to this information. CCIIO should also require plans to only list drugs on their formulary that are covered through the plan's regular process, not through an exceptions process.

- *Prescription drug non-discrimination standards must be strengthened*
  More specificity is needed in non-discrimination provisions found in 45 CFR §156.122, including explicit prohibitions on plan designs that are likely to dissuade enrollment from individuals living with chronic conditions and disabilities.

- *Co-pay accumulators must be prohibited*
  Co-pay accumulators – the practice of a plan or PBM refusing to count payments made with manufacturer co-pay cards toward a beneficiary's deductible or out-of-pocket maximum – continue to place disproportionate cost burdens on individuals with chronic conditions. The practice essentially moots the ACA's cost-sharing protections for individuals that use these co-pay cards and does nothing to save costs when applied to consumers with no other choices. CMS should limit accumulators only to situations where a generic equivalent is available.

STANDARDIZED PLAN OPTIONS

Affordability continues to be a major challenge for individuals living with chronic conditions and disabilities as plans increase use of high deductibles and co-insurance in cost-sharing designs. We ask CMS to consider the following:

- A threshold protection that would reduce affordability barriers for people living with chronic conditions and disabilities is to prohibit plans from using co-insurance. Co-insurance masks consumer cost-sharing obligations and forces individuals with higher healthcare utilization (especially higher use of specialty and brand-name medications) to pay a large amount of their healthcare costs upfront, instead of spreading out costs more evenly over the plan year.
- Alternatively, standardized plan options must include options with only co-payments instead of co-insurance, and changes should be made to 45 CFR §156.20, 155.205(b)(1) to reflect this.

- Consumers must also have the option to smooth costs across the plan year, avoiding thousands of dollars in prescription drug costs early in the year as consumers hit a deductible or out-of-pocket maximum, and allow consumers to spread prescription drug cost sharing out over a 12-month period.
- There must be additional visibility of cost sharing, particularly for plans that use co-insurance, for the consumer. This is particularly important for consumers with chronic conditions and disabilities with high health care utilization.

In addition, CMS should prohibit substitution of benefits both between and within Essential Health Benefit (EHB) categories. Substitution of benefits between EHB categories is particularly harmful to people living with chronic conditions and disabilities. For instance, plans are allowed to substitute a service in the maternal and newborn care category for an actuarially equivalent service in the rehabilitative and habilitative services category. This means that plans could reduce coverage for certain EHB categories (including ones more heavily relied upon by people with chronic conditions and disabilities) as long as it shifts coverage to other categories.

MENTAL HEALTH PARITY

The Mental Health Parity and Addiction Equity Act (MHPAEA) has been a challenge to enforce since enactment. Non-quantitative treatment limitations (NQTLs) disproportionately affect access to mental health services where no such limits exist with respect to medical services. HHS has new authority to engage in comparative analysis to review NQTLs for lack of parity and enforcement. We are pleased to see compliance with the MHPEA as part of the requirement for plans to cover mental health and behavioral health services as one of the ten Essential Health Benefits categories included in the proposed additions to the Notice of Benefit and Payment Parameters for 2022 and look forward to CMS playing a more active role in enforcing these protections.

NETWORK ADEQUACY

Access to providers with the expertise and cultural competency necessary to provide comprehensive care and treatment is essential to health equity, public health, and individual health. Protections ensuring that provider networks are able to offer care and treatment for individuals living with chronic conditions and disabilities must be strengthened. In addition to going back to the more robust network adequacy standards in place under the Obama Administration, we urge CMS to consider additional protections.

- While the essential community provider (ECP) standards are an important safeguard, CMS should strengthen this provision by requiring that any willing provider defined as an ECP should be considered in-network.
- There must be additional transparency in provider directories, with requirements for issuers to identify specialists and ECPs easily.
- Plans should be prohibited from limiting the type of provider who can serve a primary care provider. For many patients their best choice of primary care provider *is* a specialist, but plans do not always allow this.
- As CMS develops and enforces federal network adequacy standards, CMS should ensure that plans with tiered provider networks are required to meet such standards with the first tier of providers (the tier that incurs the lowest cost-sharing requirements). Providers placed on higher tiers are often inaccessible and including them in network adequacy reviews would not accurately reflect consumer experience accessing needed providers.

- CMS should require issuers to report and publicly post data on out-of-network claims to identify plans with inadequate networks.
- CMS should consider quantitative standards for network adequacy (time/distance, wait times, and provider/enrollee ratios) and specific standards for areas such as mental and behavioral health and rehabilitative and habilitative services.
- Standards regarding appointment wait times, and travel time and distance should be more robustly enforced. For instance, plans should not be deemed to have adequate networks if members cannot access a provider within reasonable means and time. Plans that do not have adequate network providers must ensure that members have access to covered benefits through a non-participating provider at no greater cost than their in-network payment.

MONITORING AND ENFORCEMENT

Consumer protections are only meaningful if they are adequately enforced. We urge CMS to dedicate additional funding from user fees to strengthen its monitoring and enforcement activities.

- Overall, CCIIO should invest more heavily in staff, systems, and procedures that will enhance plan monitoring and enforcement activities. This type of capacity building would allow CCIIO to engage in more robust compliance monitoring of QHPs and provide greater transparency on plan performance and compliance.
- As HHS develops the complaint process mandated by the No Surprises Act, it should consider opportunities to develop a broader health insurance complaint system by which to monitor the complaints originating through Marketplaces and state insurance regulators. Currently, there is no mechanism to report issues at the federal level and state insurance complaint systems are often underutilized.

CMS and state regulators should conduct direct testing of provider networks and appointment wait times to monitor compliance with federal requirements for up-to-date, accurate, and complete provider directories

Please contact Robert Greenwald with the Center for Health Law and Policy Innovation at rgreenwa@law.harvard.edu or (617) 496-9125 if you have any questions or to schedule a follow-up meeting.

The Chronic Illness and Disability Partnership (CIDP) consists of national organizations representing people living with a wide range of chronic illnesses and disabilities. We represent the 117 million Americans estimated to be living with a chronic illness and/or disability. While our organizations are national in scope, we also affiliate with strong regional, state, and community based advocacy networks.