

December 21, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-9937-P, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017

Dear Mr. Slavitt:

The Cystic Fibrosis Foundation is a national organization that funds the research and development of new cystic fibrosis (CF) therapies, invests in a CF care network that serves children and adults with CF, supports clinical data collection and health care quality improvement, and supplies a wide range of services to the entire CF community. We are pleased to have the opportunity to comment on the Notice of Benefit and Payment Parameters for 2017.

We commend the Centers for Medicare & Medicaid Services (CMS) for proposing changes in the operation of the health insurance exchanges and the standards for qualified health plans that are responsive to the needs of all consumers, including those with serious and life-threatening and chronic illnesses. We are pleased that CMS is moving toward quantitative standards for the evaluation of network adequacy and is attuned to issues of continuity of care for those with serious and chronic issues. Despite these positive steps, we remain concerned about the serious obstacles that patients with CF encounter in their efforts to obtain quality care in-network or affordable care outside their health plan's provider network. We recommend steps that might be taken to ensure CF patient access to affordable, high-quality care.

Network Adequacy Standards

For individuals with CF, a process and procedure must be established by each health plan to provide access to out-of-network CF providers according to in-network payment standards.

The assessment of minimum network adequacy standards would rely primarily on state review. Federal review, relying on time and distance standards, would occur when states decline to review network adequacy or do not adhere to a standard that will be outlined in the annual Letter to Issuers. Although the use of time and distance standards will somewhat strengthen the assessment of network adequacy, these standards are not sufficient for ensuring adequate networks for those with CF.

The agency notes the ongoing work of the National Association of Insurance Commissioners (NAIC) in developing a model act addressing network adequacy and states that CMS will “take into account the NAIC’s final recommendation as we assess these policies.” We are pleased that CMS is monitoring the NAIC process and will take that work into account as it reviews and revises network adequacy policies. We urge CMS to move without delay to evaluate and incorporate into the 2017 standards a portion of the draft model act related to access to out-of-network care. The NAIC draft model act includes a process for individuals who are diagnosed with a condition or disease “that requires specialized health care services or medical services” that are not available in-network. Under the provisions of the draft model act, a plan issuer that does not have a sufficient network of providers to provide the specialized health care services that are required by a patient shall have a process for individuals to request out-of-network care. If the individual receives care outside the network, the cost-sharing for those services will be counted toward the maximum annual out-of-pocket limit.

A process for requesting and receiving out-of-network care is critical for patients with CF. Cystic fibrosis is a genetic disease that affects multiple organs. People with CF have a defective gene that causes a build-up of mucus in the lungs, pancreas, and other organs. Thick mucus clogs the airways and traps bacteria in the lungs, leading to infections, lung damage, and respiratory failure. In the pancreas, the mucus prevents the release of digestive enzymes that allow the body to break down food and absorb vital nutrients.

Individuals with CF require a complex system of care that includes airway clearance to loosen and get rid of the mucus that builds up in the lungs, inhaled medications to thin the mucus, and pancreatic enzymes to aid in digestion. In addition, aggressive treatment is necessary when a CF patient has a lung infection. Fortunately, new drugs are being developed that address the underlying defect that causes CF. These drugs are targeted according to the genetic profile of CF patients and are currently available to about half of all CF patients. Additional drugs are in development to target more genetic mutations and treat more CF patients. The system of care to address the symptoms and causes of CF relies on a network of specialists including pulmonologists, gastroenterologists, and others.

Individuals with CF typically receive care at accredited CF care centers that are often located at academic medical centers or children’s hospitals. The care centers are also specialized in terms of providing care to children or adults. These care centers are supported and accredited by the CF Foundation, provide care according to practice guidelines and accepted medical standards, and are engaged in ongoing quality improvement efforts. The CF care centers provide CF patients the multi-disciplinary specialty care that addresses CF and all symptoms of the disease. In short, the best possible care for CF patients is available at CF care centers. However, the CF care centers are not always included in health plan networks.

In fact, CF patients in a number of states are unable to choose and purchase health insurance coverage that includes a CF care center as a network provider. Well-informed CF patients increasingly find that they cannot be assured that their caregivers will be in-network providers. For these patients, access to quality care means availing themselves of a process that grants access to out-of-network providers.

The best quality care for CF patients is in CF care centers, and a mechanism must exist to protect that access. To ensure that CF patients receive care in the best possible site, procedures must be in place to guarantee out-of-network care when necessary. As noted above, cost-sharing for such care should be counted toward the maximum annual out-of-pocket limit and that the benefits are in fact treated as in-network benefits.

We look forward to revision of network adequacy standards so that they would require the inclusion of CF care centers as in-network providers. However, because such a result is unlikely in the immediate future, CF patients must have protections for out-of-network access.

We note with approval that CMS has articulated protections against so-called “surprise” balancing billing for out-of-network services provided in an in-network setting and continuity of care protections for a patient when his or her a provider is terminated from a network without cause. These protections are important but do not address the fundamental access issue for CF patients, which is the ability to obtain care at a CF care center, even if that center is out-of-network, as if the CF care center services were in-network.

Prescription Drug Benefits

For individuals with CF, it is critical that plans have an efficient exceptions process for obtaining off-formulary drugs and an appeals process for any on-formulary drug denials.

Prompt access to prescription medications is critical to CF patients, who depend on medications for treatment of a wide range of symptoms of CF. In addition, prescription drugs approved in recent years address the fundamental defect that causes CF. Patients need these drugs without delay, as interruptions in care and lack of access to medications may contribute to declines in lung function.

For CF patients, it is important that the drugs prescribed by their physicians are included on health plan formulary lists and that processes be established for addressing any obstacles to coverage. In addition, there must be a strong coverage appeals process for those drugs that are listed on formulary but may be denied to individual patients, as well as an exceptions process for obtaining drugs that are not included on a plan’s formulary list.

The preamble language on standards for the exceptions process for obtaining off-formulary drugs is unclear, and no regulatory language is included in the proposed rule. We urge the agency to establish a strong federal exceptions process for off-formulary drugs and that the federal process should be a floor. State laws that are more stringent than the federal standard and that provide patients strong protections for obtaining off-formulary drugs should be enforced above the federal floor.

Standardized Options

Standardized plan options should not include specialty pharmacy tiers with burdensome cost-sharing requirements that slow or block access of CF patients to life-saving drugs.

We support the effort to standardize plan options, as fewer and more predictable plan options may improve consumer choice of plans. However, we have concerns about the standards that have been articulated for certain of the standardized options.

We commend the effort to make certain services deductible-exempt in the standardized option designs. For example, the exemption of primary care visits, specialty visits, and prescription drugs from the application of deductibles in most circumstances improves the standardized plan options.

We note several exceptions to the concept of deductible-exempt service. Specialty visits are not exempt from deductibles in the standardized bronze plan and neither are drugs, except for generic drugs. In addition, the standardized plan options include a specialty drug tier. Although specialty drugs are exempt from deductibles in all standardized options except the bronze plan, coinsurance percentages, instead of copayments, would be applied in the specialty drug tier. Many, if not most, CF drugs are on specialty drug tiers. The coinsurance requirements for these drugs have a significant impact on the behavior of CF patients and the quality of care they receive. Data indicate that patients adjust to the financial burdens associated with specialty tier cost-sharing by skipping doses of drugs or forgoing treatment altogether. We urge the agency, as it continues the development of standardized plan options, to include copayments in place of coinsurance for prescription drugs, and abandon the utilization of specialty tiers.

The Roles and Responsibilities of Navigators and Assistants

Navigators who assume additional post-enrollment activities will require high-quality training and should also be directed to collaborate with patient-centered and community-based organizations that also provide insurance and health care counseling services.

We commend CMS for reconsidering the roles of Navigators and assistants. We support the provisions of the proposed rule that would: 1) require Navigators in exchanges to provide targeted assistance to serve underserved and/or vulnerable populations and 2) require Navigators to provide certain post-enrollment assistance. The marketplace for insurance choice and utilization is changing, and it is important for consumers to have the skills for plan decision-making and for management of their health care.

As CMS seeks to expand the roles of Navigators and assistants, we urge that attention be directed to the training that these individuals receive for their expanded roles, and that the Navigators be trained regarding the issues which they should not address and those for which a referral to other experts is necessary. These would include, for example, legal advice and services and tax advice related to insurance coverage.

We also urge CMS to consider strategies for the Navigators to collaborate with patient-focused and community-based organizations that are also engaged in health consumer and patient education. We think that this collaborative approach could be encouraged through guidance to the Exchanges. Patient and community organizations can complement the work of Navigators in post-enrollment activities.

We appreciate the opportunity to comment on the standards for Exchanges and health plans in 2017. We look forward to continued efforts to strengthen health plans so they are responsive to the needs of those with serious chronic illnesses.