

CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS
ADDRESSING PUBLIC POLICY ISSUES IN CANCER

December 22, 2014

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: CMS-9944-P, Proposed Rule on Notice of Benefit and Payment Parameters for 2016

Dear Secretary Burwell:

The undersigned organizations represent cancer patients, health professionals, and researchers. Many of the individuals represented by our organizations have purchased qualified health plans (QHPs) through the health insurance exchanges, and their access to quality care depends on the adequacy of those health plans. We appreciate the actions that the Department of Health and Human Services (HHS) has outlined for plan year 2016 and years after that would strengthen key elements of QHPs. We offer advice on a number of these proposals and on the move toward more transparency in reporting QHP data. We commend HHS for taking important steps to protect consumers in the health insurance exchanges.

Essential Health Benefits: The Benchmark Approach

We are pleased that the proposed rule would update the benchmarking approach to definition of essential health benefits (EHB) by requiring states to choose a 2014 plan as the benchmark plan beginning in 2017. We urge the department to utilize the health plan data that it will require to be reported – beginning with 2014 plan year information – to inform efforts to move beyond the benchmarking approach and to provide specific department guidance about EHBs. We also recommend that reliance on 2014 benchmark plans be effective for the 2016 plan year, an implementation schedule that we understand is ambitious.

Prescription Drug Benefits: Establishing a More Robust Formulary

We commend HHS for its thoughtful approach to improving prescription drug formularies in QHPs. HHS states that its proposal for formulary development would result in QHP coverage of drugs “based on a qualitative rather than quantitative perspective, which we believe will provide enrollees with a more robust formulary drug list.” In the current plan year, many enrollees with cancer have found that the drugs they have been prescribed are not on their plan’s formulary. If

these patients cannot obtain access through the exceptions process, they must make difficult choices about their treatment. Some have responded by altering their treatment plan and others by paying out-of-pocket for off-formulary drugs. These choices just underscore that QHP formularies may fall short for cancer patients and others with serious and life-threatening illnesses.

HHS suggests that a formulary process combining utilization of the American Hospital Formulary Services (AHFS) formulary reference system and a pharmacy & therapeutics (P&T) committee system will result in a more robust formulary in each QHP. The P&T committee standards defined in the proposed rule are strong. HHS sets forth rules for P&T membership, management of conflicts, and frequency of P&T committee meetings. In addition, the proposed rule includes standards for P&T deliberations. Specifically, the proposed rule states that, “With respect to formulary drug list establishment and management, we are proposing that the P&T committee must develop and document procedures to ensure appropriate drug review and including on the formulary drug list, as well as make clinical decisions based on scientific evidence, such as peer-reviewed medical literature, and standards of practice, such as well-established clinical practice guidelines.” A P&T committee that deliberates according to these standards will make an important contribution to the development of a QHP formulary.

Although the P&T committee standards provide some reassurance about QHP formulary development, we have questions about the AHFS and about the manner in which AHFS listings and the P&T committee system will relate. HHS states that the AHFS is a “widely used formulary reference system in the private insurance market and is often used for developing formularies for the population being covered by EHB.” Moreover, HHS states that AHFS has more drug classifications than the United States Pharmacopeia system that has been used to date and that utilization of the AHFS will result in a broader distribution of drugs on the formulary. In spite of the assurances of HHS, we are concerned that the AHFS is not adequate in its cancer drug classifications.

We recommend instead that the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium be referenced for development of the oncology portions of a QHP formulary. The NCCN Compendium is used by a number of payers, including the Centers for Medicare & Medicaid Services and private payers, to guide coverage decisions, and describes the evidence that is utilized to make usage recommendations. QHP formulary drug lists developed by use of the NCCN Compendium and a strong P&T committee system would be more likely to meet the cancer care needs of QHP enrollees than the formularies in many current plans.

Exceptions Process

The recommended improvements in the exceptions process will provide cancer patients important protections. We commend the department for establishing a standard exceptions process, which must be completed in 72 hours, in addition to the expedited exceptions process that requires action in 24 hours. In addition, patients will benefit from the secondary external review process that will be available if the first exception request (whether standard or expedited) is denied by the plan.

The proposed rule offers another consumer protection by requiring that drugs covered through an exceptions process be considered essential health benefits and counted toward the out-of-pocket cost-sharing maximum.

Formulary Drug List Transparency

Consumers will be served well by the requirement that health plans publish an “up-to-date, accurate and complete list of all covered drugs on its formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained.” HHS asks for advice regarding the inclusion of cost-sharing information, including the pharmacy deductible, copayment amounts, or cost-sharing percentage, on the formulary drug list. We recommend that such information be included.

HHS has indicated that it is considering a requirement that issuers make information about formulary drug lists available on their websites in a machine-readable file and format identified by HHS. The department indicates that imposing this data requirement would permit third parties to aggregate information on a range of health plans. Consumer access to aggregate information of this sort would help to transform the insurance marketplaces into patient- and consumer-friendly plan selection and purchasing options.

Prohibition on Discrimination

We commend the department for addressing the topic of discriminatory benefit design and identifying designs that might be discriminatory. However, noting the problem of discriminatory plan design is not sufficient. We urge HHS to take more concrete regulatory action against discriminatory benefit design. This is a matter of urgency for cancer patients, who confront discriminatory benefit packages that place most or all cancer therapies on specialty tiers.

Network Adequacy and Cost-Sharing Requirements

The narrow provider networks in many health plans serve in some situations to block cancer patient access to appropriate care. For many individuals with rare cancers or cancers with limited treatment options, the best option may be to pursue care at a cancer center with special expertise in the cancer or from another health system that treats a high volume of cases of the specific cancer. Children with cancer may also have the best treatment options in children’s hospitals or other health care systems with experience and expertise in childhood cancer. In those circumstances, it is possible that those treatment options are out-of-network. A decision to pursue out-of-network care is likely accompanied by significant patient cost.

HHS must address network adequacy problems by requiring health plans to maintain networks that are adequate for treatment of complex, rare, or hard-to-treat diseases or providing financial protections to patients who must pursue out-of-network care. The department has taken modest but insufficient steps on network adequacy in the proposed rule for 2016. We understand that the department is relying on the National Association for Insurance Commissioners (NAIC) effort to define standards for network adequacy, an effort that we will also be engaged in.

HHS states that plan issuers may count cost-sharing for out-of-network services toward the annual limitation on cost-sharing. However, encouraging this effort is far from a requirement that issuers do so. As a result, we expect little financial protection for patients who receive care out-of-network. The department would require plan issuers to permit new enrollees access to their network of providers for 30 days after enrollment in the new plan. This transitional protection would be useful to patients but far from the network adequacy standards they need.

We also support the proposal to strengthen the provider directory requirement, which would mandate that issuers publish an up-to-date, accurate, and complete provider directory. Supplying this information will help consumers make informed decisions about their health plan and will also assist them in managing their care after enrollment. Although information for consumers is a positive, this requirement does not address the matter of network adequacy.

Habilitative and Rehabilitative Services for Cancer Patients

We are pleased that HHS is moving to define habilitative services, and we think that the definition of habilitative services as “health care services that help a person keep, learn, or improve skills and functioning for daily living” is a viable definition. Some of the supportive care services that are provided to cancer patients during cancer treatment fit squarely within this definition. These include nutritional support services to maintain good nutrition during radiation therapy and chemotherapy, mental health services to address issues of anxiety and depression, and services to address the psychosocial issues that patients confront during treatment.

We applaud the decision to require plan issuers to treat habilitative services as a different category from rehabilitative services, a decision that will prevent the application of a single limit on services to the combination of habilitative and rehabilitative services.

Data Collection

Consumers, patients, and the entire health system will benefit from the collection and availability of data from 2014 plans, and we support the decision to make these data available. For maximum benefit to be achieved from release and use of these data, they should be displayed in a simple and consistent manner across plans.

HHS indicates that information about enrollments, disenrollments, claims denials, and cost-sharing for out-of-network care will be collected and made public. We recommend that data on both appeals and exceptions processes also be collected and published. These categories of data may provide some perspective on the adequacy of benefits for individuals with cancer and other serious illnesses and whether the exceptions and appeals processes are providing patients an avenue for access to necessary care. We have concerns that cancer patients may change their treatment choices or even forgo treatment if care is not available on-formulary or in-network, and the appeals and exceptions data may help with investigating and understanding this problem.

Quality Improvement Strategy

Beginning in 2016, plans that have participated in the exchanges for two years would be required to report on their quality improvement strategy (QIS) plans. HHS has directed issuers to implement a payment structure that would improve health outcomes, reduce hospital readmissions, improve patient safety and reduce medical errors, implement wellness and health promotion activities, and reduce health and health care disparities. We urge HHS to provide guidance to plans to structure their reimbursement plans in a way that emphasizes care planning and care coordination for cancer patients and others with serious chronic illnesses. A payment plan that emphasizes these elements of care delivery will also contribute to health outcome improvement, readmission reductions, patient safety improvements, and a reduction in medical errors.

We appreciate the opportunity to comment on the Notice of Benefit and Payment Parameters for 2016. We look forward to the implementation of QHP standards outlined in this proposed rule, as they promise modest but steady progress toward stronger health plans for enrollees.

Sincerely,

Cancer Leadership Council

American Society of Clinical Oncology
CancerCare
Cancer Support Community
The Children's Cause for Cancer Advocacy
Fight Colorectal Cancer
Hematology/Oncology Pharmacy Association
International Myeloma Foundation
Kidney Cancer Association
The Leukemia & Lymphoma Society
LIVESTRONG Foundation
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
National Comprehensive Cancer Network
National Patient Advocate Foundation
Ovarian Cancer National Alliance
Prevent Cancer Foundation
Sarcoma Foundation of America
Susan G. Komen