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Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attn: CMS-9980-P
P.O. Box 8010
Baltimore, MD 21244-8010

To Whom It May Concern:

The American Cancer Society Cancer Action Network ("ACS CAN") is the advocacy affiliate of the American Cancer Society (the "Society"). The Society is a nationwide, community-based, voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives, and diminishing suffering from cancer through research, education, advocacy, and service. The Society is the largest voluntary health organization in the United States.

ACS CAN appreciates the opportunity to provide comments to the U.S. Department of Health and Human Services on the proposed regulation: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Our organization views the essential benefits package as one of the most important tools in the fight against cancer. Too often we hear stories of cancer patients who have insurance but who discover too late that their coverage is inadequate to provide the evidence-based care they need. Arbitrary benefit limits or the total lack of coverage of vital benefits can leave a cancer patient with the morally unacceptable choice of abandoning necessary care or facing financial ruin. Cancer is approximately 200 different diseases with widely varying causes and potential treatments. Thus, defining "essential" just for cancer is a formidable process, and obviously there are many serious medical conditions that ultimately need to be covered effectively. Through the essential benefits package provision, HHS, we and many other interested parties are embarking on a critical national discussion about what is "essential." The task is daunting but extraordinarily important. We applaud the department and its staff for their effort and thoughtfulness in preparing the proposed regulation.

Comments

Definitions of categories (§156.20)

The Affordable Care Act specifies 10 categories that must be included in the essential health benefits package.[1] Congress explicitly intended these categories be considered essential health benefits that ensure access to comprehensive coverage—especially for conditions that are not covered or covered inadequately in the individual and small-group markets.

HHS should precisely define the scope and services within each of the 10 benefit categories. Because traditional plans do not categorize their services within the same benefit categories or use the same terminology, it is unclear how the essential health benefits package could be compared to potential benchmark plans in an effort to ensure that it complies with the ACA. For example, "ambulatory patient services" is not a category that is commonly seen in commercial plans, and it is unclear what specifically would need to be covered to satisfy HHS' standards.

Many of the 10 ACA categories, such as Mental Health and Substance Use Disorders, Rehabilitative and Habilitative care, Maternity and Newborn Care, and Pediatric Oral and Vision Care, are examples of conditions or service categories that are specifically included within Section 1302 of the ACA to correct longstanding gaps in coverage that consumers face in the individual and small-group markets. It is imperative that HHS provide clear standards for what must be covered under each category to establish a standard that would be used to compare proposed state benchmark plans. An example of an important concern to cancer patients is physician-administered chemotherapy, which is common for many forms of cancer. We assume chemotherapy is an example of a critical benefit that should be explicitly defined as an element of a category.

The proposal allows some insurer flexibility within, but not among categories, which is a desirable and appropriate policy. However, critical benefits such as chemotherapy for cancer should not be left to chance or an insurer's preference. The categories must be defined in a manner to ensure such critical benefits are clearly required in all EHB plans. Because the 10 categories are not well defined, there is the potential for consumer confusion and possible gaming by insurers to engage in risk selection through benefit design. Allowing a state or insurer to define these categories would erode the intent of Section 1302 of the ACA and enhance the potential for discrimination.

[1] These categories include: Ambulatory patient services; Emergency services; Hospitalization; Laboratory services; Maternity and newborn care; Mental health and substance use disorder services, including behavioral health treatment; Pediatric services, including oral and vision care; Prescription drugs; Preventive and wellness services and chronic disease management; and Rehabilitative and habilitative services and devices.

ACS CAN is particularly concerned about allowing benefit limits. The department has said that specific service limits are permissible, but these limits should not be incorporated wholesale into the EHB package. Arbitrary and unreasonable limits can be used to restrict needed care – inconsistent with the ACA's clear intention to guarantee that at least the 10 benefit categories are consistently covered – or steer consumers into or away from certain plans. In some instances, arbitrary service limits could seriously interfere with necessary care. For example, ACS CAN learned of a group plan that had a limit of 35 doctor visits a year, but a breast cancer patient in the plan required chemotherapy once a week for a year, in addition to other doctor visits that were necessary to treat her cancer fully and properly. This particular patient wound up with $135,000 in out-of-pocket expenses for her cancer. Under the ACA, these expenses would not count toward the cap on annual out-of-pocket spending that the law requires of non-grandfathered plans in the individual and small-group markets beginning in 2014.

Recommendation:

- The 10 categories of coverage should be defined more clearly so that insurers, regulators and consumers better understand what benefits are essential. Consumers need explicit assurance that vital benefits like chemotherapy for cancer patients are essential and must be provided as part of an essential benefits package.

Covered state mandates (§155.170)

We applaud the decision to cover all state-required benefits enacted on or before December 31, 2011 within a state's essential benefits package. The preamble states that the rule would apply to benefits "...specific to the care, treatment, and services that a state requires issuers to offer to its enrollees." The preamble further states that mandated benefits that relate to cost-sharing or reimbursement methods would not fall under the department's interpretation of state-required benefits.

An issue of importance to cancer patients is oral parity. Twenty states and the District of Columbia have passed oral chemotherapy parity legislation to help equalize patient out-of-pocket costs for oral chemotherapies and IV chemotherapies. These laws generally require state-regulated health insurance companies and group health plans to cover orally administered anticancer drugs "on a basis no less favorable than" IV-administered ones. The number of drugs in these classes are likely to grow significantly in the next few years as there are many oral cancer drugs in development and potentially close to final FDA approval.

Recommendation:

- We strongly recommend that the regulatory language state clearly that if a cost-sharing mandate also affects treatment and care, that it be covered. The oral parity mandate is a treatment and care benefit as well as a cost-sharing benefit. We are very concerned that ambiguity in the language will confuse and potentially harm cancer patients. This could result in delays and possible litigation if the decision is left to insurers and state regulators to resolve. (We are not aware of any other mandates that so clearly straddle both categories.)

Prescription Drug Coverage

Prescription drug coverage is extremely important to cancer patients. An analysis of the medical expenditure panel (MEPS) data pooled from 2007-2009 suggests the importance of drugs in treating cancer. Of the approximately 6 million non-elderly, non-Medicare people with a history of cancer whose data were captured during this period, half had at least 10 unique prescriptions and 23 percent had at least 25 unique prescriptions. Moreover, approximately 9 percent had at least one prescription costing at least $500 out of pocket.[2]

In 2010, the U.S. Pharmacopeia Convention (USP) developed a list of categories and classes for the Medicare Part D Manual to be used by prescription drug plans for covered Part D drugs. The USP category of Antineoplastic drugs—which are used for treatment of cancer—and the 10 distinct USP classes of antineoplastic drugs are classified based on how the drugs prevent and inhibit the growth of specific types of cancer. All drug coverage in plans covered by the EHB must be presented using the USP classification system.

Failure to include all the drugs in each of the USP classes within each of the USP categories of drugs may result in gaps in coverage of one or more drugs that treat a particular cancer. For example, the USP Molecular Target Inhibitors class within the Antineoplastic drug category has a total of 11 drugs[3] that treat more than 11 unique types of cancer. However, the benchmark plan for Colorado covers only five molecular target inhibitor drugs. The drugs in a class are not always clinically interchangeable. Thus, there is likely to be a significant gap in treatment coverage of at least six remaining types of cancer. Furthermore, for many molecular target inhibitor drugs, there are no effective alternative traditional chemotherapy treatments. Cancer patients in Colorado may not have the necessary access to the full array of treatment options available in such formularies as the Federal Employee Health Benefits Program which covers all drugs available in the USP class. For cancer patients with limited formularies, the choice is either to pay substantially higher out-of-pocket costs because drugs not in the essential benefits package will not be subject to cost-sharing and annual out-of-pocket limits, or to forgo the most appropriate drugs, risking a worse health outcome. A review of some of the other state benchmark plans suggests that the Colorado example is not unique.

The use of the USP classifications is understandable given that the concept of essential benefits is so new, and that understanding "typical" coverage today in the private health insurance market is difficult. However, it is important to note its shortcomings in both the context of the benchmark system as well as the foundation for a longer-term basis for determining prescription drug coverage. Specifically, the USP is:

- Only updated every three years. This means that it could take three years to list new FDA-approved drugs.

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[2] Reidy, Erin. 2012. "Frequency of Health Care Use by Cancer Patients." ACS CAN. http://www.acscan.org/content/wp-content/uploads/2012/11/MEPS-Cancer.pdf

[3] Avalere Health LLC. (October, 2012). Drug Coverage in Essential Health Benefits Benchmark Plans: Formulary Analysis, October 2012. State Reform. Retrieved December 3, 2012, from http://www.statereforum.org/node/10589

- Designed for Medicare Part D. Thus, many of the needs of a younger population are not fully addressed.
- Excludes physician-administered drugs (e.g., most chemotherapy drugs for cancer treatment). Because they are covered under Medicare Part B, they are not currently listed in the USP.
- Excludes biologics and biosimilars that are becoming increasingly important in cancer care.

The importance of prescription drugs is likely to increase dramatically in the coming decade. Traditionally, cancer patients are given chemotherapy for the treatment of many forms of cancer. The drugs are administered by infusion by a health professional. However, in recent years there have been advancements in oral drugs which may be a substitute for or a supplement to chemotherapy. Currently, there are more than 40 FDA-approved oral cancer drugs, and there are more than 900 cancer drugs currently in development. Many of these new drugs could become available in the next few years, offering great potential for improvements in care and quality of life for cancer patients. Furthermore, many of these cancer medications have become the standard of care for treating patients with certain cancers, are *only* available in oral form and have no IV equivalent. This may be especially true in the future as more cancer drugs are approved.

The proposed regulation in this section states, "A health plan providing essential health benefits must have procedures in place that allow an enrollee to request clinically appropriate drugs not covered by the health plan." In light of the shortcomings in the USP and the incomplete status of many state benchmark plan formularies, this provision is inadequate. The department should be more prescriptive on the process and the timeline for decisions. The quality of prescription drug coverage could be a matter of life or death for patients; therefore, a more proscriptive approach to quickly and equitably resolving questions of coverage is imperative. For example, plans could be required to update their formularies using methods similar to Medicare Part D and the private insurance market. Part D requires that independent Pharmacy and Therapeutic (P&T) Committees make decisions on coverage of new products within 180 days of their approval. As part of the requirement to review newly approved drugs, patients in plans subject to the EHB should be able to remain on older therapies without the fear that their prescriptions will be taken off the formulary when a newer drug is added.

Finally, the structure of the prescription drug benefit has profound long-term cost implications for both cancer patients and the federal government. Because oral cancer drugs are relatively new, only a few generics are available. Existing brand drugs are extremely expensive and the drugs in the pipeline are likely to be comparably expensive. Thus, the inclusion (or exclusion) on the EHB formulary will have a profound impact on access to these newer cancer drugs because of the interactions with the cost-sharing and out-of-pocket limits that apply to essential benefits. And access can affect the quality of care and health outcomes. Today, a patient's out-of-pocket costs for some oral cancer medications can easily exceed $400 per month. A recent study conducted by Avalere Health found that 25% of cancer patients with a prescription for an

oral cancer drug exceeding $500 per month abandoned their prescription.[4] Establishing the best possible prescription drug standard now is critical for the health and well-being of cancer patients.

Recommendations:

1. The state benchmark plan's drug formulary should be only a floor. A plan can have a higher number of drugs in a class. Moreover, a plan should be able to add to any drug class at any time and have the drugs considered covered as essential benefits. The Part D model for updating formularies should be considered for application to benchmark plans for 2014 and 2015.
2. The drug classification system underlying the EHB must reflect the full needs of the expected plan population.
3. The rule should include specific requirements for plans to assure patients access to medically necessary drugs that are not on a plan's formulary. The requirements should include provisions for immediate review and temporary coverage while appeals are being reviewed.

Benchmark plan selection and standards (§156.100)

The development of the benchmark plan approach is a pragmatic decision to address a very formidable and unprecedented task of determining "essential" health benefits. However, ACS CAN is extremely concerned that deferring the definition of the EHB package to the states rather than having a nationally defined set of EHB services is a missed opportunity for several reasons. First, this approach will make it more difficult to promote value- and evidence-based cancer care to all Americans. This will be particularly true in 2014 and 2015, when each state's EHB package will be based on the benefits offered by the selected benchmark at the time of its selection. We are concerned that this essentially means that benefits will not be updated during this time to reflect advances in science and medical evidence.

The rule proposes that plans may have limitations on coverage that differ from the EHB-benchmark plan (including limits on amount, duration, and scope of covered benefits) but covered benefits must be actuarially equivalent to those covered by the EHB-benchmark plan. Earlier in this letter, we expressed concern about the inclusion of limits in the definition of covered benefits. We are also concerned that it will not be possible to verify the actuarial equivalence of treatment limits. It is not clear that a determination of actuarial equivalence can be made for a specific benefit limit (as opposed to a package of benefits and cost-sharing). And even a limit that is actuarially equivalent when measured for a standard population could be grossly inadequate for many individual consumers.

Recommendation: Summary plan documents or insurance contracts for benchmark plans should be posted on healthcare.gov and exchange web sites for qualified health plans, and state insurance departments should be encouraged to make them available on their web sites or other appropriate sites for consumers. Full disclosure of critical documents is a vital first-step toward

[4] Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions. The American Journal of Managed Care. May 2011. Vol. 17. SP28-SP44. Accessed at: [http://www.sph.umich.edu/vbidcenter/publications/pdfs/abandonment_of_oral_oncolytic_rx.pdf].

educating and empowering consumers to more effectively engage in their health care and public discussions about the health care system.

Provision of EHB (§156.110)

The rule proposes that plans may have limitations on coverage that differ from the EHB-benchmark plan (including limits on amount, duration, and scope of covered benefits) but covered benefits must be actuarially equivalent to those covered by the EHB-benchmark plan. Earlier in this letter, we expressed concern about the inclusion of limits in the definition of covered benefits. We are also concerned that it will not be possible to verify the actuarial equivalence of treatment limits. It is not clear that a determination of actuarial equivalence can be made for a specific benefit limit (as opposed to a package of benefits and cost-sharing). Individual plans may not have sufficient data to reliably estimate "value" within a reasonable margin. Moreover, even a limit that is actuarially equivalent when measured for a standard population could be grossly inadequate for many individual consumers. (The AV calculator does not capture the service limits affect, which in some circumstances might be significant. This is a technical problem that should be addressed in future versions of the calculator.)

HHS' proposal also provides significant flexibility by allowing each state to set a different benchmark benefit standard. Giving insurers the additional ability to vary from each state's standard would be highly problematic by further diluting the EHB requirement.[5] It is unclear what advantage, if any, the proposal for "flexibility" holds for consumers. If insurers can substantially vary the details of the benefits they cover from a state's chosen benchmark benefits standard, consumers will have a difficult time comparing the features of different plan options and making informed decisions about coverage. In addition, some insurers would likely exercise this flexibility to impose problematic benefit restrictions (such as visit limits) that would shift costs to people with significant or rare health care needs. Insurers would thus be able to construct their plans in ways that discourage enrollment by high-cost people or attract enrollment by people who are less costly to cover.

HHS justifies the proposed approach to benefits flexibility for insurers by stating it "would provide greater choice to consumers, promoting plan innovation through coverage and design options…" Upon critical examination, neither justification is compelling.

Consumer behavioral research in general—and with respect to insurance choices specifically—shows that too much choice does *not* benefit consumers. In fact, having too many options *reduces* consumers' willingness to make a selection.

Health insurance is a particularly difficult product for consumers to assess.[6] Extensive consumer testing in Massachusetts, after the state implemented an insurance exchange called Commonwealth Choice, found that the ideal number of plan designs in the exchange was six to nine. In Massachusetts, plan design differed mainly in plan cost-sharing charges (with minor

[5] Note to commenters: Some may want to insert a discussion about the problems of having a different standard in each state rather than a consistent standard.

[6] Quincy,Lynn "What's Behind The Door: Consumers' Difficulties Selecting Health Plans," Consumers Union, January 2012.

exceptions), and even then consumers favored a limited number of choices.[7] Consumers were *not* clamoring for variation in covered services to be added to the list of variables. The Utah Health Exchange, which is based on an approach that allows all insures who meet minimum standards to participate, offers more than 140 plan options.[8] The Utah Health Exchange, as of August 1st 2012, covered a total of 6,800 lives. Early research indicates that when employees enter the exchange, they gravitate toward familiar plans.[9]

Much of the "innovation" that insurers would want to incorporate into their products is likely to be related to cost-sharing details, incentives to use particular providers, disease management programs, and utilization management techniques. These would be separate from the essential health benefits requirements proposed in the bulletin and would not be hampered by consistent benefit requirements.

Recommendation: At a minimum, plans must disclose clearly on their web sites the methods and assumptions used in determining actuarial equivalence for each benefit. This information should also be required to be submitted to the state's exchange (including Federally-Facilitated Exchanges) and insurance department. The exchange or the insurance department should have the clear authority to reject a plan's methods and related switches in benefits.

Provision of preventive services in EHB (§ 156.115)

ACS CAN appreciates the clarification that a plan required to offer the EHB must provide all preventive services described in §147.130 without cost-sharing, as we recommended in previous comments. The ACA is very clear that the process for defining and updating these services and their definition is outside of the EHB process. The recommendations of the U.S. Preventive Services Task Force (USPSTF) and other entities, as required by statute may include how often a certain preventive service should be provided. Given the incorporation of such details in the definitions of these services, any limits allowed as a part of the EHB cannot be applied to the Section 2713 preventive health services. For example, tobacco cessation services are given an "A" recommendation from the USPSTF, but because several attempts are usually necessary to successfully quit smoking, the frequency and duration of treatments should not be limited. Similarly, screening for and management of obesity are given a "B" recommendation from the USPSTF for both adults and youth age six and older, but access to the recommended duration, frequency, and types of counseling and intensive behavioral management should not be contingent upon achieving a certain amount of weight loss within a specified time period. Limiting the benefit with preauthorization requirements, restrictions on treatment settings or treatment providers, or other unreasonable limits deters people from using these preventive services and should be prohibited unless consistent with the recommendations of the entity given responsibility in the ACA for defining them.

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[7] *Health Reform Toolkit Series: Resources from the Massachusetts Experience, Determining Health* Benefits Designs to be offered on a State Health Insurance Exchange, Massachusetts Health Connector, November 2011.

[8] States in Action Utah Health Exchange, The Commonwealth Fund March 2011 http://www.commonwealthfund.org/Newsletters/States-in-Action/2011/Mar/February-March-2011/Snapshots/Utah.aspx

[9] The State of the Utah Health Exchange, Utah Health Policy Project September 2011 http://www.healthpolicyproject.org/Publications_files/State/TheStateOfUHEDashboard.pdf

An examination of many of the state benchmark plans suggests that it is often very unclear what preventive health services are covered and what the limits on this coverage may be. For instance, many plans merely include a blanket statement such as "preventative services mandated by the ACA are covered," but do not explicitly define what those services are. Current coverage of tobacco cessation helps illustrate our point about why further definition of preventive services is needed under the final EHB rule to ensure that comprehensive services are available. Tobacco use is responsible for an estimated 443,000 deaths each year and accounts for at least 30 percent of all cancer deaths and 80 percent of lung cancer deaths.[10][11] Stopping tobacco use leads to increased employee productivity, less disability and chronic disease, and reductions in medical expenditures. Increasing the number of successful attempts to stop tobacco use will have an important effect on health and health care costs. Tobacco users vary in what tobacco products they use, how much, how often, and in what coexisting medical conditions they may have. When quitting, they need access to a range of treatments, both medication and counseling, to find the most effective tools that work for them. The covered benefit should include all over-the-counter (OTC) and prescription medications approved by the FDA (including combination use) and multiple face-to-face counseling sessions conducted by a qualified health professional.

Despite the evidence that supports coverage of tobacco cessation and the fact that the USPSTF recommendation covers both pharmacotherapy and counseling for tobacco cessation, current health plan coverage of these services is very uneven. In our examination of the proposed EHB benchmark plans, 20 states' benchmarks appear to cover no medications for tobacco cessation. The benchmarks of 18 states make no mention of tobacco cessation in the summary plan information made available on the CMS website. We recognize that does not mean these services are not covered, but we wonder how other plans required to provide the EHB will know exactly what they must cover?.

A recent study conducted by the Georgetown University Health Policy Institute for the Campaign for Tobacco-Free Kids also found inconsistencies in the coverage of tobacco cessation services in the contracts they examined of plans required to comply with Section 2713 of the PHS Act.

- While 36 contracts indicated that they covered tobacco cessation or are providing coverage consistent with the USPSTF recommendations, 26 of these contracts also included language entirely or partially excluding tobacco cessation from coverage.
- There was wide variation in coverage for cessation counseling and medication, raising concern that treatments found to be effective by the USPSTF and required under the ACA are not being covered. Only four of the 39 plans stated they covered individual, group and phone counseling, and both prescription and OTC medications. Many policies specifically excluded certain types of counseling and provided no coverage of prescription and OTC medications for tobacco cessation.
- In apparent conflict with the ACA, some policies included cost-sharing requirements. Seven of 36 contracts that clearly covered counseling required cost-sharing for

[10] Centers for Disease Control and Prevention. Smoking-attributable mortality, years of potential life lost, and productivity losses-United States, 2000-2004, *MVR Morb Mortality Weekly Report* Nov. 14 2008; 57(45):1226-1228.
[11] Doll R, Peto R. *The Causes of Cancer,* New York, N.Y.: Oxford Press; 1981.

counseling by in-network providers, and six of 24 contracts that covered prescription drugs required cost-sharing.[12]

Screening for and management of obesity in adults and youth are additional examples of preventive services requiring more specificity about the services covered and the population that has access to the covered services. The USPSTF recommends that all adults and youth ages six and older be screened for obesity, and that obese adults be offered or referred to "high intensity multicomponent behavioral interventions" and obese youth to "moderate to high intensity counseling and behavioral interventions to promote improvement in weight status". These terms should be further defined based on additional details in the USPSTF recommendation statements,[1314] the most recent clinical guidelines from the National Heart, Lung, and Blood Institute (which are currently being updated),[15]16 and other relevant guidelines from public health and professional associations about the frequency and duration of sessions and the types of counseling and behavioral interventions most likely to lead to weight loss.

As this information illustrates, we need more specificity and detail on the preventive services covered by the base-benchmark plan in order to accurately evaluate it, and consumers will need this information in order to take full advantage of these benefits. The final rule should require issuers providing the EHB to specifically list what preventive services are covered and state that coverage is provided without imposing any cost-sharing. With respect to tobacco cessation, guidance issued by the Office of Personnel Management (OPM) for the Federal Employees Health Benefits Program is an excellent model for HHS to use to help define the scope of coverage required by the ACA. OPM has instructed insurers to cover at least two quit attempts per year with up to four cessation counseling sessions of at least 30 minutes each (including individual, group and phone counseling). They must also cover OTC and prescription medications.

The cessation and obesity management issues illustrate a larger problem about the USPSTF guidelines. The Task Force makes determinations on the appropriateness of preventive measures, but it does not address how screenings or preventive measures should be implemented—and implementation is the crux of whether the service is ultimately effective or not. We have seen problems with the implementation of the USPSTF guidelines for other "A" and "B" rated services, including breast and colon cancer screenings. In each case there are different methods and approaches that can be employed but the appropriateness may vary depending on the needs of the patient. A one-size-fits-all approach does not work well; yet, the health plan has no obligation under the existing regulation on preventive services or this proposed rule to make different options available.

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[12] Kofman, M., Dunton, K., and Senkewicz MB. "Implementation of tobacco cessation coverage under the Affordable Care Act: Understanding how private health insurance policies cover tobacco cessation treatments." November 26, 2012. Accessed online at: http://www.tobaccofreekids.org/pressoffice/2012/georgetown/coveragereport.pdf.

[13] x[13] Moyer, VA, on behalf of the USPSTF. "Screening for and management of obesity in adults: U.S. Preventive Services Task Force recommendation statement." *Annals of Internal Medicine* 2012; 157:373-378.

[14] USPSTF. "Screening for obesity in children and adolescents: US Preventive Services Task Force recommendation.

[15]

National Institutes of Health, National Heart, Lung, and Blood Institute. *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults.* September 1998. NIH Publication No. 98-4083.

Further, the USPSTF guidelines are developed only for standard risk populations. This is a huge shortcoming and of particular concern in the fight against cancer. The American Cancer Society (the Society) has done extensive research on prevention and vulnerable populations and has identified high-risk groups where screening is deemed appropriate, and these are groups that are not recommended for services under the standard risk population recommendations of the USPSTF. HHS should consider ways in which the evidence-based guidelines of other groups such as the Society can also be used as the standard for coverage of prevention services and have them deemed part of the EHB.

We applaud HHS for proposing in the rule that substitution of benefits across benefit categories would be prohibited. We also support the clarification that states have the authority to prohibit benefit substitution altogether or to enforce a stricter standard for substitution. However, we continue to be concerned that issuers would still be allowed to substitute benefits or sets of benefits that are actuarially equivalent within benefit categories. The EHB standard in the ACA is intended to ensure a consistent, minimum level of benefits across all non-grandfathered, fully-insured plans in the individual and small-group insurance markets so consumers can make an apples-to-apples comparison of plan options and insurers cannot adopt benefit designs intended to attract healthier people and deter enrollment among those in poorer health. The proposal to allow variation within benefit categories would undermine these goals.

Recommendations:

- Prevention services that are required to be covered (i.e., USPSTF "A" and "B" recommendations) cannot be limited to a wellness program. For example, a person wanting to participate in smoking cessation services cannot be restricted to programs offered through an insurer's or employer's wellness program.
- HHS should promulgate guidance on coverage and scope of acceptable tobacco cessation services.
- HHS should review other sources of evidence-based guidelines for prevention services and allow health plans to use them for defining scope of coverage under the EHB. As noted, the USPSTF does not address the needs of high-risk populations or the operational aspects of their recommended services should be provided.

Anti-discrimination prohibition ((§ 156.125)

ACS CAN strongly supports the requirements that an insurer not discriminate in its benefit design, application of its design, or marketing practices. The anti-discrimination provision of the ACA is a vital backstop to the many other provisions that advance the statute's goals of access to and adequacy of coverage. The law envisions, and the proposed regulation supports, some degree of flexibility in the essential benefit package, but based on our experience representing people with cancer, we know that insurance plans can be designed to deny those with chronic diseases access to medically necessary and evidence-based care.

Recommendation:

- The Department should establish more specific reporting and disclosure requirements for benchmark plans. Information on EHB plan design and variation, and specific benefits, enrollment, and other pertinent information could be enormously valuable to the department and the public in developing a more robust and nationally-based essential health benefits for 2016 and beyond, as well as helping indentify potentially discriminatory designs and practices, consistent with the intent of §156.125.

Essential health benefits post-2015

The concept of an essential health benefits package is unprecedented, and the ACA provides only the basic structure. Therefore, the benchmark plan process is an appropriate step toward implementing this new and vastly important process. As the essential health benefits package evolves, it will become the focus of health care for much of the nation's insurance coverage, reaching far beyond the individual and small group market.

As the Department proceeds with the implementation of the benchmark plans, it is imperative that it also focus on the EHB post-2016. As noted above, ACS CAN strongly believes that essential health benefits should be generally uniform in all states. The benefits available to cancer patients should not fundamentally vary depending on where one lives. (The delivery of benefits may vary to some degree based on geography and other factors, but the benefits should not vary). The proposed rule is clear that the benchmark approach is transitional and changes may be made in a few years based on experience and more data.

More specifically, a post-benchmark EHB should:

- *Create a long-term process for reviewing and revising the EHB on a national basis.* ACS CAN supports the creation of an ongoing advisory committee(s) or another process that would monitor the EHB implementation and make recommendations for updating the EHB package to address gaps in coverage and to evaluate benefit designs and service trends. This approach would also allow the EHB package to be adjusted to reflect advances in medical evidence or scientific advancement. The advisory panel should include experts with a wide range of medical expertise that represent the health care needs of diverse segments of the population.
- *Address innovation and how new drugs and technologies will be incorporated.* What is the standard for approval? How will new and effective cancer drugs get added to the formulary so that they are covered by the EHB and therefore subject to the ACA cost-sharing and out-of-pocket limits?
- *Develop a drug formulary that is evidence-based.* Drugs are often not interchangeable even within the same class. The cancer drugs are complex and potent, and increasingly, they are targeted to specific forms of cancer. A numeric standard as set forth in this proposal is entirely unacceptable as a long-term policy.
- *Prohibit benefit limits and develop evidence-based care benefits:* A benefit limit—a de facto annual limit—is contrary to the intent of the law and the goal of promoting effective care and better health outcomes. The EHB should be structured to encourage evidence-based care rather than allowing arbitrary benefit limits.

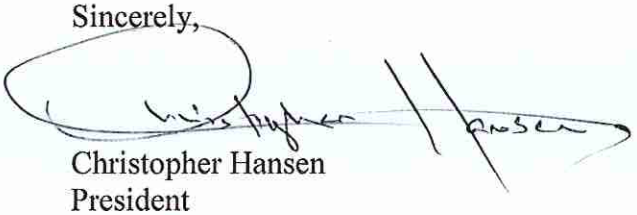
- *Replace or modify the USP*: The use of the USP, though acceptable for immediate use, is not an adequate framework for assessing drug coverage in the long-run. The USP was developed to support Medicare Part D plans so it reflects the needs of an older population than will be generally covered by the EHB. Moreover, the USP does not address multiple compound drugs or physician-administered drugs, which is most chemotherapy.
- *Establish standards for using evidence-based guidelines other than those of the USPSTF for coverage of prevention services under the EHB.* As noted above, the USPSTF guidelines do not address implementation issues or high risk populations in their recommendations, and these shortcomings significantly undermine the potential gains that can and should be made by the requirements in ACA to provide coverage of evidence-based prevention services.

The final regulation or another formal statement by the department should indicate how and when the department will begin to consider these longer-term critical policy issues.

Thank you again for the opportunity to share our comments on this critical proposal. The proposal represents an exceptional effort by the department to begin a vital national discussion about the true meaning of essential health care.

If you have any further questions, you may contact Stephen Finan, Senior Director of Policy for ACS CAN, at Stephen.Finan@cancer.org or 202-661-5780.

Sincerely,



Christopher Hansen
President