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December 22, 2014

The Honorable Sylvia Burwell
Secretary
Department of Health and Human Services
Attention: CMS-9944-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-9944-P –Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters for 2016
79 Fed. Reg. 70673 (November 26, 2014)

Dear Secretary Burwell:

The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

ACS CAN supports many of the provisions outlined in the proposed rule. We appreciate HHS' proposed changes to the Special Enrollment Periods (SEPs). In addition, we urge HHS to require SEPs for formulary and provider directory changes, as well provide a new SEP for loss of employer-sponsored coverage to be retroactive to the date of the loss of employment.

However, as discussed in more detail below, we are concerned the proposed changes to the re-enrollment hierarchy focuses on a plan's premium, rather than looking at the totality of the plan's coverage and cost-sharing requirements. Auto-enrollment based on a lower cost plan could put a cancer patient at risk for significantly higher out-of-pocket costs.

Regarding HHS' proposed changes to the qualified health plans' (QHP's) prescription drug benefits, we urge HHS to require plans to use the most current version of the U.S. Pharmacopeia (USP) as a benchmark, but allow plans to supplement with the use a pharmacy and therapeutics committee to ensure that enrollees have access to the prescription drugs to meet their needs.

Finally, we are concerned about a plan's network adequacy standards. While we appreciate HHS' recognition of the work currently being conducted by the National Association of Insurance Commissioners (NAIC) with respect to this important topic, we urge HHS to promulgate additional federal network adequacy standards and to vigilantly monitor the extent to which enrollees use out-of-network services as a proxy for the adequacy of the plan's network.

C. Part 147 – Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Guaranteed Availability of Coverage (§ 147.104)

HHS proposes to amend the existing rules to allow a special enrollment period (SEP) for a qualified individual (and dependents) whose individual health insurance policy is offered on a non-calendar year basis. Current HHS rules allowed a SEP only for 2014.

ACS CAN supports the HHS proposal. This policy will help to ensure that individuals do not experience a gap in their health care coverage. Even short gaps in coverage can lead to significant disruptions in care for individuals with cancer.

2. Guaranteed Renewability of Coverage (§ 147.106)

HHS is considering how to interpret the ACA's guaranteed renewability provisions in the context of various corporate transactions which involve a change in ownership (e.g., mergers, acquisitions, or other business restructuring). The Preamble notes that HHS seeks to establish standards that will ensure seamless coverage for enrollees. HHS suggests it could allow for the retention of enrollees under a product that is undergoing a change in ownership but only if the same benefits, network, and other coverage features remain in place.

ACS CAN appreciates HHS' attempt to ensure that enrollees whose plan changes ownership mid-year experience a seamless transition between the two plans. It is imperative that if plan ownership were to change mid-year, the new plan must provide the same benefits (including premiums, cost-sharing requirements, appeal rights), network, and coverage features provided under the original plan. The enrollee should be subject to the same formulary and provider network under the new ownership. In short, from the perspective of the enrollee, there should be no change in the plan other than a change in the plan's name.

Enrollees should be provided notice of the change in ownership that clearly articulates that the beneficiary's coverage remains unchanged and that he/she is not required to take any action. HHS must ensure that any appeals or exceptions (whether internal or external) pending at the time of the change in ownership are addressed on an expedited basis so that the enrollee's access to medically necessary products and services are not hampered by the plan's change in ownership.

In addition, we note that some enrollees have opted to enroll in an auto-payment option for their monthly insurance premiums. We urge HHS to require that plans that change ownership make a concerted effort to ensure that any auto-payment policies are not negatively impacted, and to specifically provide these individuals with information on how to change their auto-payment of premiums prior to the change in ownership.

E. Part 153 – Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Under the Affordable Care Act

2. Provisions and Parameters for the Permanent Risk Adjustment Program

c. Proposed Updates to Risk Adjustment Model

HHS proposes to recalibrate the risk adjustment model by updating risk adjustment factors using newly acquired claims data for 2010, 2011, and 2012. In addition, HHS proposes that if 2013 data become available after the publication of the rule, those data be incorporated in this update so that the HHS risk adjustment model is taking into account the three most recent years of data available.

ACS CAN supports this proposal and appreciates HHS' recognition of the importance of a sound and robust risk adjustment program. We support CMS' effort to update and recalibrate the models by incorporating the newest information. The incorporation of more recent data, including data for 2013 should it become available, into the model should boost issuers' confidence in the model's predictive power which, in turn, could reduce risk selection behaviors and helps to stabilize premiums.

3. Provisions and Parameters for the Transitional Reinsurance Program

g. Uniform Reinsurance Contribution Rate for 2016

HHS proposes to establish a hierarchy for payments in the event that collections for 2016 fall short of payments needed for the benefit year. In the case that collections exceed needed payments, HHS seeks comment on whether such funds should be allowed to roll over to the 2017 benefit year.

ACS CAN supports HHS' proposal that any funds that remain beyond those needed for the 2016 benefit year roll over to the 2017 benefit year. This policy will allow for a slightly longer period for plans to adjust to their risk pools to ensure maximum premium stability.

F. Part 154 – Health Insurance Issuer Rate Increases: Disclosure and Review Requirements

2. Disclosure and Review Provisions

a. Rate Increases Subject to Review (§ 154.200)

Currently, a rate increase in the individual or small group market is subject to review by HHS if the rate increase is 10 percent or more, or if the rate increase exceeds a State-specific threshold. HHS proposes to require consideration of rate increases at the plan level – not the product level – in determining whether an increase is subject to review. Thus, if any plan within the individual or small group market meets or exceeds the threshold, the product (including all plans within the product) would be subject to review. The rate increase would trigger review even if the average increase for the product itself did not meet or exceed the threshold amount.

ACS CAN supports HHS' proposed policy to review rate increases at the plan level. Congress adopted the rate review policy to monitor the extent to which plans' premiums significantly increase. We are pleased that this proposed policy will ensure that rate increases are determined on an individual plan basis so that HHS can continue to monitor whether an individual's plan exceeds the threshold. The proposed policy ensures issuers who offer multiple plan products could not significantly increase premiums on one product and avoid a rate review if the combined increases in the issuer's other products did not exceed the 10 percent threshold.

At the same time, we urge HHS to decrease the rate review threshold amount from 10 percent to a figure that is more in line with increases in health care expenditures. Over time, these rate increases could quickly become unaffordable for individuals. In addition, this problem is compounded for older Americans – who are at a higher risk of developing cancer – who can be subject to higher health care premiums due to the statutory provision allowing plans to impose 3:1 age rating.

d. CMS's Determinations of Effective Rate Review Programs (§ 154.301)

HHS proposes to modify the criteria used to determine if a State has an Effective Rate Review Program. HHS proposes to require the State to have a mechanism for receiving public comments on the proposed rate increases and requiring the State to post on its website information about proposed and final rate increases (rather than allowing the State the option to simply provide CMS' web address for such information). HHS is considering requiring States to post proposed rate increases within 10 business dates after receipt of all rate filings and the final rate increases to be posted no later than the first day of the annual enrollment period.

ACS CAN supports HHS' proposal that States be required to post proposed rate increases, but we are concerned that the 10 day proposal may not be adequate time to provide review and comment. We urge HHS to consider requiring States to provide at least 30 days for public notice and comment.

G. Part 155 – Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

2. General Functions of an Exchange

a. Consumer Assistance Tools and Programs of an Exchange (§ 155.205)

HHS proposes to require Exchanges, qualified health plan (QHP) issuers, and web-brokers to make telephone interpretation available in at least 150 languages; proposes additional detail on how to provide meaningful access to those with limited English proficiency; and, establishes that critical forms must be provided in at least 150 languages. These standards would not apply to Navigator and non-Navigator services.

ACS CAN supports HHS' proposed policy, which will help provide necessary information to consumers for whom English is not their primary language. While we believe this requirement is appropriate for QHPs, web-brokers, and Exchanges, we also agree with HHS that it is premature to impose the requirement on Navigators and Non-Navigators. As noted in the Preamble, many Navigator grants were awarded to entities that lack sufficient resources to be able to comply with the requirement to provide information in 150 different languages. However, in the future, HHS may wish to consider whether to require or encourage Navigators to utilize telephone interpretation services that have the capability of translating into more than 150 different languages.

c. Standards for HHS Approved Vendors of Federally-Facilitated Exchange Training for Agents and Brokers (§ 155.222)

For 2014 and 2015, HHS has provided training agents and brokers in federally-facilitated exchanges (FFEs). HHS proposes that for 2016 and future years, HHS-approved vendors could provide such training, as long as the organization submits an application and can demonstrate it meets certain standards. Vendors would be approved on a yearly basis, subject to a re-approval process for additional years to be determined by HHS.

Ensuring that consumers have access to accurate information is vitally important. Consumers shopping in the Marketplace often have complex coverage issues. Thus in addition to the myriad rules regarding QHPs, agents and brokers also must understand the complex eligibility rules for the Medicaid, Children's Health Insurance Program (CHIP), and Medicare programs. While the proposed rule would require that vendors adhere to HHS specifications for content, format, and delivery of training and information verification, we urge HHS to require vendors to submit to HHS any consumer materials prior to their publication or release so that the Department can verify the validity of that information.

If HHS were to outsource the training of agents and brokers, we strongly urge HHS to maintain vigilant oversight of the vendors to ensure that consumers are being provided accurate and timely information, including such mechanisms as implementing a "secret shopper" program so HHS can validate the information being provided to consumers. There are lessons to be learned from the early days of Medicare Part D implementation when many beneficiaries received erroneous information from personnel who had been poorly trained. Vendors who are found to be providing misinformation and/or steering consumers to select plans should have their contract immediately terminated. In addition, HHS should clarify whether if an entity's contract were to terminate, to what extent individual agents and brokers employed by the terminated entity would be permitted to serve customers in the Marketplace through another vendor.

Finally, we urge HHS to amend the proposed special enrollment periods (SEPs) to explicitly provide for an SEP in instances where outside vendors provided (whether intentionally or unintentionally) misinformation to consumers who relied on that information when making their plan selections.

3. Exchange Functions in the Individual Market: Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

a. Annual Eligibility Redetermination (§ 155.335)

Currently, enrollees who do not choose a new plan for themselves at the start of a new benefit year will be automatically re-enrolled into the same or similar plan for the following year. HHS is exploring whether, beginning in 2017, an enrollee could, at the time of initial enrollment, be given a choice of re-enrollment hierarchies that could be triggered in the event the enrollee's plan premium increases. HHS suggests one of these hierarchies could be that an enrollee could choose to be defaulted into the lowest cost plan at their metal level or randomly assigned into one of three low cost plans. HHS notes that any re-enrollment hierarchy would be trumped if the enrollee were to affirmatively choose a plan themselves at re-enrollment.

ACS CAN appreciates that the proposed policy is intended to make it easier for consumers to re-enroll in QHP coverage. However, we are concerned the proposed policy could actually negatively impact enrollees. The Preamble notes that plan premiums change on a yearly basis, but more importantly to cancer patients, coverage and cost-sharing also change between plan years. Therefore, an individual who is automatically re-enrolled into a lower-premium plan could end up paying significantly more in total out-of-pocket costs for their care because the plan has higher cost sharing. For many cancer patients (including those who may be newly diagnosed, are in active treatment, or survivors) coverage

and cost-sharing are greater factors than the plan's premium.[1] Auto-enrollment based only on a lower cost plan could put a cancer patient at risk for significant out-of-pocket costs.

We also note that defaulting an individual into the lowest-premium plan could result in individual having to switch health insurers. As a result, the individual may face a significantly different network of providers and/or cost-sharing obligations. This is particularly problematic for cancer patients who often rely on specialized physicians and hospitals in which to access necessary care.

Under the proposed policy, absent a change in life events significant enough to warrant an SEP, the individual would be unable to choose a more appropriate plan until the following plan year. Unfortunately for a cancer patient, this could mean having to incur significant out-of-network costs (which may or may not be included as part of the maximum out-of-pocket spending) in order to receive necessary care.

We urge HHS not to move forward with the proposed auto re-enrollment policy. Alternatively, if HHS chooses to implement the policy, we strongly urge the Department to provide a SEP to individuals who were auto-enrolled into a policy whose coverage and cost-sharing significantly increases from one year to the next. Further, HHS should provide extensive notice – on healthcare.gov, in printed materials and to Navigators – about auto-enrollment.

4. Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

b. Annual Open Enrollment Period (§ 155.410)

HHS proposes that for benefit years on or after January 1, 2016, the annual open enrollment period would begin on October 1st and extend through December 15th of the calendar year preceding the benefit year. Coverage would be effective on January 1st of the year following the open enrollment period.

ACS CAN supports HHS' proposal to standardize the annual open enrollment period, which will help simplify the annual enrollment period for consumers and entities that assist consumers in choosing a QHP to best meet their needs. We believe this enrollment period will allow plans significant time to update their systems to capture all enrollees before the start of the plan year.

We note that the Medicare annual election period begins on October 15th and ends December 7th each year. As HHS continues to monitor the implementation of the QHPs, in future years we would urge the Department to consider whether the Marketplace open enrollment period and the Medicare annual election period should be concurrent.

[1] ACS CAN encourages cancer patients to focus on other aspects of the plan – like co-sharing, covered benefits and in-network providers – before focusing on the plan's premium. See American Cancer Society Cancer Action Network, Tips for Choosing the Right Health Insurance Plan, available at http://www.acscan.org/content/wp-content/uploads/2013/10/Tips-for-Choosing-Health-Insurance.pdf (updated October 2014).

c. Special Enrollment Periods (§ 155.420)

HHS proposes a number of changes to the special enrollment periods (SEPs):

Permanent move. HHS proposes that beginning January 1, 2016, consumers who are eligible for an SEP due to a permanent move would be permitted advanced access to the SEP. This policy would allow the consumer to obtain coverage on the first day of the month following the move, provided the individual selects a new plan before or on the day of the loss of coverage.

ACS CAN supports this proposed SEP because it would help to ensure that individuals who move would not experience a gap in their health insurance coverage. Some cancer patients may choose to move from one area to another in order to access specialized cancer treatments. In such cases, these patients would benefit from an SEP that would ensure they do not experience a gap in their health insurance coverage.

Death of an enrollee. HHS proposes to require Exchanges to ensure that coverage is effective the first day of the month following the death of the enrollee or his/her dependent. When a consumer dies in the middle of the month, issuers could either continue to provide coverage for the enrollment group through the end of the month or could align the date of coverage with the date of death (though the latter option would require proration of premiums and advance payments of the premium tax credit).

ACS CAN supports this proposal. However, we are concerned the SEP only applies to individuals who had health insurance coverage through the Marketplace. We urge HHS to also provide this SEP to individuals who had coverage outside the Marketplace (e.g., employer-sponsored coverage). This SEP will ensure that individuals do not experience a gap in their health insurance coverage.

Non-calendar year plans. HHS proposes to allow individuals in non-calendar year plans (e.g., transitional plans, early enrollment plans, or group plans) to enroll in Exchanges when their coverage ends.

ACS CAN supports this proposal, consistent with the § 147.104 policy discussed above.

Divorce. HHS proposes to create an SEP for enrollees who lose a dependent or lose dependent status as a result of legal separation, divorce, or death of the enrollee.

ACS CAN supports this proposed policy, which will help to ensure that individuals whose health insurance coverage changes due to legal separation, divorce, and death do not experience a gap in health insurance coverage. However, we are concerned the SEP only applies to individuals who had health insurance coverage through the Marketplace. We urge HHS to clarify this SEP is also available to individuals who had coverage outside the Marketplace (e.g., employer-sponsored coverage).

Misrepresentation or error. HHS proposes to amend the current SEP for non-Exchange entity misconduct and replace it with an SEP where enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous, and is the result of the error, misrepresentation, or inaction of an officer, employee, or agent of the Exchange, HHS, or its instrumentalities. HHS notes that this SEP would also pertain to actions made when a non-Exchange entity is providing enrollment assistance.

ACS CAN strongly supports HHS' proposal. In § 155.222, HHS proposes to allow approved vendors to provide training to agents and brokers. We urge HHS to clarify that this proposed SEP would also apply in instances where HHS-approved vendors provide erroneous or misinformation to consumers (if HHS finalizes its proposed § 155.222 policy).

As discussed in more detail below, we note that some provider directories may contain erroneous information. We urge HHS to clarify that individuals who rely on provider directories in choosing a plan should not trapped in that plan if it later is determined that the plan directory was inaccurate with respect to the providers and services covered by the plan.

As HHS finalizes this policy we urge the Department to provide additional guidance to consumers regarding what, if any, proof needs to be provided to an Exchange in order to qualify for this SEP. Given that there still exists confusion among consumers regarding the Exchanges, we urge HHS in its guidance to provide lenient standards upon which individuals can obtain this SEP.

Non-Medicaid expansion states. Unfortunately not all states have expanded their Medicaid programs, as provided under the ACA. Individuals who reside in these non-expansion states whose income is below the threshold to qualify for advance payments of the premium tax credits (APTCs) are often unable to afford health insurance coverage. During the year, some of these individuals experience an increase in their household income and thus would qualify for an APTC. Unfortunately under current rules these individuals do not have an SEP in order to access a Marketplace plan with an APTC. HHS proposes a SEP to allow a qualified individual in a non-Medicaid expansion state a SEP if that individual later experiences a change in household income making them newly eligible for an APTC.

ACS CAN strongly supports this provision. We are strong advocates for Medicaid expansion and are actively working to encourage expansion in States that have not yet done so. Low-income individuals in non-expansion states are left with few, if any, options for obtaining health insurance coverage. If such individuals experience an increase in household income, they should be able to obtain health insurance coverage through the Marketplace using advance payments of the premium tax credit.

Other SEPs. In addition to the SEPs proposed by HHS, ACS CAN offers the following SEPs for consideration:

SEP due to loss of employment: ACS CAN urges HHS to consider creating a SEP allowing individuals who lose employer-sponsored coverage to enroll in a Marketplace plan with coverage retroactive to the last date of employer sponsored coverage. Coverage provided under this SEP would be pro-rated based on the number of days of coverage provided by the plan. While individuals are entitled to an SEP if they experience a loss in coverage due to loss of employment, under the current rules coverage in a Marketplace plan would not begin until the first day of the following month. The American Cancer Society operates a specialized Health Insurance Assistance Service (HIAS) which provides cancer patients information about health insurance options that may be available to them in their area. HIAS representatives often hear from individuals who lose their job (without prior notice) and as a result, lose their insurance coverage that same day. Under current rules, the individual (and his/her dependents) would face a gap in coverage unless they elect COBRA, which is prohibitively expensive for many individuals. Even short gaps in coverage can lead to disruptions in care and significant out-of-pocket costs for patients with cancer, so it is imperative that individuals who lose their jobs be able to begin coverage mid-month if necessary.

SEP for formulary changes: We urge HHS to create a SEP for individuals whose plan increases cost-sharing or coverage for a prescription drug currently taken by the individual. Currently, issuers are permitted to change their prescription drug formularies during the plan year. As a result, a cancer patient who may have chosen a plan based in large part on the cost-sharing associated with their oncology drugs may find that the plan no longer covers the prescription drugs that are medically

necessary to meet the needs of the individual. In such instances, unless the individual experiences a life event that qualifies for another SEP, the individual would be trapped in a plan that does not meet their needs, and would incur significant out of pocket costs until a new plan could be obtained in the next plan year.

SEP for provider changes: We urge HHS to create an SEP for individuals who are currently in active treatment if their plan's alteration to the provider network results in the individual's provider being no longer covered under the plan or if the plan increases the cost-sharing to access a given provider. Cancer patients in active treatment depend on the advice and care provided by their oncologist and specialized cancer centers.

d. Termination of Coverage (§ 155.430)

Currently enrollees have the option to terminate their coverage in a QHP. HHS proposes to clarify that enrollees' right to terminate would be determined by the appropriate state law (including "free look" cancellation laws). HHS also proposes to require Exchanges to establish a process for a third party, such as the consumer's authorized representative, to report the death of a consumer.

ACS CAN supports HHS' proposal to allow a third party to report the death of a consumer to the QHP. However, we are concerned with HHS' proposal to defer to state laws pertaining to an individual's right to terminate their coverage. We are concerned that deferring to the States – particularly on such an important consumer protection as the right to terminate coverage – may result in inconsistent consumer protections across state laws. Thus, we urge HHS to promulgate federal standards and allow States the option to exceed such standards if they so desire.

H. Part 156 – Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

2. Essential Health Benefits Package

c. Collection of Data To Define Essential Health Benefits (§ 156.120)

HHS proposes to allow each State to select a new base-benchmark plan for the 2017 plan year, based on plans available in 2014.

ACS CAN appreciates HHS' acknowledgement of the need to update state benchmark plans. However, we note that plans available in plan year 2014 were based in large part on plans available in the year 2012. These existing state benchmark plans do not include state mandates that may have been enacted in a given state since 2012. We are concerned that if HHS' benchmark process continues to rely in part on standards enacted in 2012, it can create a chilling effect for States wishing to enact additional state mandates since States are responsible for incurring the cost of any mandates enacted since 2012.

While we recognize the complexity of the benchmarking process and HHS' need to finalize this rule quickly, we urge HHS to revisit the benchmarking issue in the near future. We note that under current essential health benefit (EHB) standards, plans are required to cover the same number of prescription drugs in each category and class as the EHB benchmark plan or in classes not covered by the benchmark plan, one drug in every United States Pharmacopeia (USP) category and class. If the benchmark does not change significantly from one year to the next, we are concerned the benchmark will not adequately reflect new categories and classes of drugs – including important cancer drugs – which may impede consumers' access to these products.

d. Prescription Drug Benefits (§ 156.122)

Use of P&T committees: Currently QHPs are required to cover the greater of one drug per United States Pharmacopeia (USP) category or class or the same number of drugs in each USP category and class as the state's EHB benchmark plan. HHS proposes to replace this count standard with a new requirement that plans, beginning in 2017, adopt a pharmacy and therapeutics (P&T) committee that would ensure the plan's formulary drug list covers a sufficient number and type of prescription drugs. HHS proposes P&T Committee standards. HHS notes that if this policy were finalized, States would be responsible for the oversight and enforcement of the standards (given that States are responsible for enforcing EHB requirements).

ACS CAN supports HHS' proposal to allow plans to use a P&T committee in determining the prescription drugs available under the plan's formulary. However, we do not believe the P&T committee should be used as a replacement to the current USP requirement. Rather, the P&T committee should be used as a supplement to a benchmark. We believe that using the P&T committee in combination with the minimum USP standard allows plans to have the flexibility they need with respect to their formulary designs while at the same time ensuring that the formulary is sufficiently robust to ensure that enrollees have access to the prescription drugs necessary to treat or ameliorate their diseases or conditions.

With respect to the construction of the P&T committee, we urge HHS to adopt many of the requirements that currently exist in the Medicare Part D program. For example, we urge HHS to require that P&T committees be required to review any new drug within 30 days of market entry to determine whether the drug should be included the plan's formulary.

Regarding conflict of interest requirements, the Medicare Part D program requires that P&T committee members be independent and free of conflict of interest with respect to the issuer and pharmaceutical manufacturer (though members may have a consulting relationship with issuers and pharmaceutical manufacturers, provided those relationships do not constitute a significant source of the committee member's income). We urge HHS to require that any P&T committee members that have a stated conflict of interest be prohibited from voting on matters for which the conflict exists. Finally, we urge HHS to require issuers to ensure that a statistically significant percentage – at least 50 percent – of committee members be free of conflict of interests with the issuer or any pharmaceutical manufacturer.

In addition, we urge HHS to set minimum standards for P&T committees, including a minimum number of individuals who serve on the committee. A recent HHS Office of Inspector General report noted that Medicare Part D plan sponsors' P&T committees ranged in size from 3 to 62 members, with an average size of 16 members.[2] We urge HHS to require that plans' P&T committees contain a minimum number of members to ensure robust representation. We would encourage HHS to consider requiring P&T committees to have at least 15 members.

[2] HHS Office of Inspector General (OIG), *Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions*, OEI-05-10-00450, March 2013.

USP vs. AHFS: As an alternative (or supplement) HHS also is considering whether to replace the USP standard with a standard based on the American Hospital Formulary Service (AHFS). The Preamble notes that the AHFS is widely used on the private insurance market.

ACS CAN urges HHS to retain the USP standard as a benchmark, but to allow plans to develop the formulary through use of the P&T committee. With respect to cancer care, the USP standard provides more coverage of oncology drugs. The USP standard would require plans to cover 10 classes of antineoplastic (oncology) drugs, while the AHFS standard would result in only 1 class of antineoplastic drugs to be covered. However, we note that for other diseases or conditions the AHFS standard may be more robust. As a public policy matter it is not helpful to have different disease states or conditions benefit from one standard versus another. Given there are winners and losers under each standard, HHS should review the extent to which the USP standard may not adequately provide coverage for a given disease or condition and specifically require a plan – for example, through its P&T committee – to ensure adequate coverage of the major disease or condition.

At the same time, we note that the USP standard is updated only once every three years while the AHFS is updated on an annual basis and posts updates throughout the year. In order to ensure that enrollees have access to the most recent prescription drugs to meet their needs, it is imperative that plans be required to adopt the most recent version of the USP as part of their benchmark standard. Therefore, we urge HHS to require plans to adopt the most recent USP standard once it is finalized. For example, we note that the USP version 6.0 adds an additional class of antineoplastic drugs, antiandrogens, which includes drugs to treat prostate cancer, and nearly doubles the number of drugs in the molecular target inhibitors class from 12 in the current HHS drug count service to 22.[3]

Formulary exceptions: HHS proposes to standardize an exception request for an expedited review so that an enrollee can gain access to a clinically appropriate drug that is not on the plan's formulary. Under the proposal, the plan must make its coverage decision and notify the enrollee (or her designee or physician) of the decision within 72 hours after receiving the request. Coverage would be provided for the duration of the prescription (including refills) and the coverage would be considered an EHB for purposes of applying cost-sharing limitations. Plans would be required to act on expedited requests within 24 hours. If a plan denies the exceptions request, the issuer must have a process for an independent review organization review of the request and its denial. HHS proposes this policy could begin as early as the 2016 plan year.

ACS CAN supports HHS' proposed expedited review policy and strongly urges its adoption for plan year 2016. Cancer patients often require the use of a plan's exceptions process in order to obtain products and services necessary to treat their condition. We appreciate HHS' acknowledgement that expedited exceptions must be conducted within 24 hours and non-expedited exceptions within no more than 72 hours. In addition, ACS CAN supports the requirement that plans make available an external, independent review process when necessary.

We strongly support HHS' requirement that if a prescription drug is covered pursuant to the exceptions process the coverage would be considered an essential health benefit and thus any cost-sharing associated with the drug would count towards the enrollee's maximum annual out-of-pocket limit. We

[3] American Cancer Society Cancer Action Network, Cancer Drug Coverage in Health Insurance Marketplace Plans, (March 2014), available at http://www.acscan.org/content/wp-content/uploads/2014/03/Marketplace_formularies_whitepaper.pdf.

encourage HHS to further clarify that if an enrollee maintains his/her current plan from one plan year to the next, the enrollee would not have to undergo an exception to have his/her drug covered in subsequent plan years. In other words, an enrollee who remains with the same plan and who successfully receives an exception for coverage of a medically necessary prescription drug should not have to file an exception each plan year in order to maintain coverage of the affected drug, so long as the drug is medically necessary.

Formulary exceptions can be an important tool for individuals, like cancer patients, who need access to specific, high-cost treatments. It is imperative that individuals (and their families and caregivers) be informed of how to utilize a plan's formulary exceptions process. Therefore, we urge HHS to require all plans to provide consumer-friendly, plain language information explaining how an individual can utilize this process. This information should be prominently displayed on the plan's public website so that enrollees and members of the public can access this information.

Formulary transparency requirements: HHS proposes to require health plans to make public a current, accurate, and complete list of all covered drugs on its formulary drug list, including tiering structure and any restrictions. This list must be easily accessible to enrollees, prospective enrollees, the public, and other stakeholders and be made available on the plan's public website through a clearly identifiable link or tab. HHS is considering requiring the formulary to be made available in a machine-readable file or submitted through an HHS designated standardized template.

ACS CAN strongly supports this increased prescription drug formulary transparency. We recommend that HHS require all Marketplaces to collect and display prescription drug formularies, including drugs covered under the medical benefit, in a comparable, consistent, and searchable manner. While HHS has greatly improved the availability of formularies through the healthcare.gov website, we encourage HHS to require plans to provide prescription drug formulary information in a machine-readable, standard format to better allow consumers to make apples-to-apples comparisons of plans.

We urge HHS to develop and implement a tool similar to the Medicare Plan Finder tool, that provides beneficiaries (and the public) access to a tool where beneficiaries can enter prescription drugs and see examples of out-of-pocket costs for each plan option (whether a stand-alone Part D plan or a Medicare Advantage plan). While we recognize that it may take time for HHS to develop this platform, we urge its adoption as soon as possible, with an aim of completion in time for the plan year 2017 annual enrollment period.

Retail pharmacies: HHS proposes to require that enrollees have the option to access their prescription drugs through retail pharmacies (including brick-and-mortar or non-mail order pharmacies). Plans still would be permitted to charge higher cost-sharing when enrollees obtain the drug at an in-network pharmacy compared to using mail order pharmacies. HHS clarifies that this additional amount would count towards the plan's annual limit on cost-sharing and would need to be taken into account when calculating the actuarial value of the plan.

ACS CAN supports this proposed policy. While we support mail order pharmacies as an option for consumers, we recognize that not all prescriptions are appropriate to be filled through mail order and in-network retail pharmacies should be available to consumers who choose to utilize that service. For example, cancer patients often need access to pain medications and may be unable to wait for the prescription to be filled via mail order pharmacy.

We also support HHS' clarification that cost-sharing associated with prescriptions filled at in-network pharmacies would count toward the individual's annual limit on cost-sharing. While the proposal would allow plans to charge a higher cost-sharing for utilizing in-network pharmacies compared to mail order pharmacies, we urge HHS to monitor the cost difference between filling a prescription at a mail order pharmacy versus an in-network retail pharmacy to ensure that the in-network retail pharmacy cost-sharing is not so prohibitive as to create an access burden for individuals to utilize in-network pharmacies.

Continuity of coverage: HHS is considering, though not requiring, that plans temporarily cover non-formulary drugs during the first 30 days of coverage for individuals who, upon enrollment, are taking drugs that have been prescribed.

ACS CAN strongly urges HHS to make this proposed policy a requirement – not an option – for plans. This policy which will ensure that individuals can maintain access to their prescription drugs for a period of time while they switch from one plan to another. However, we would encourage HHS to require that plans extend the continuity of coverage provisions in cases where the enrollee has filed an appeal to have the affected drug covered under the plan and the appeal has not yet been completed (including the option for an external review process, if warranted).

In addition, we are concerned that proposed 30 days of coverage may be insufficient in some cases. We urge HHS to consider expanding this requirement to provide for 60 days of coverage. We also urge HHS to require that plans that make mid-year formulary changes allow enrollees who are currently taking the affected prescription drug to continue to take that drug without having to undergo an appeals process throughout the remainder of the plan year. We note the Medicare Part D program provides a similar requirement.[4]

e. Prohibition on Discrimination (§ 156.125)

HHS notes that it is not proposing any new anti-discrimination rules under this proposed rule. The Preamble discusses examples of benefit designs that discourage enrollment based on age or health condition. HHS specifically cautions issuers to avoid discouraging enrollment of individuals with chronic health needs (e.g., placing all or most drugs for a particular treatment on the highest tier). HHS reiterates that CMS will notify an issuer when a reduction of the generosity of a benefit for a subset of individuals that is not based on clinically indicated, reasonable medical management.

ACS CAN is disappointed that HHS has yet to issue regulations that further define the ACA's anti-discrimination requirements. As noted in the Preamble, some groups have expressed concern that a handful of issuers are including benefit designs that on its face appear to be discriminatory to a particular disease group. Simply cautioning issuers may not be sufficient protection to ensure that the intent of the ACA's anti-discrimination provisions is not violated. We urge HHS as soon as possible to promulgate regulations providing additional insights into the tools the Department will use to determine whether these requirements are met.

[4] CMS, *Medicare Prescription Drug Benefit Manual*, Ch. 6 – Part D Drugs and Formulary Requirements, (Rev. 10, 02-19-10) § 30.3.3.1.

f. Cost-Sharing Requirements (§156.130)

Non-calendar year plans: HHS proposes that non-calendar year plans be required to adhere to the annual limitation on cost-sharing that is applicable to the calendar year in which the plan begins. Non-calendar year plans would not be permitted to reset the plan's annual limitation at the end of the calendar year if that is not also at the end of the plan year.

ACS CAN supports this requirement, which will prohibit non-calendar year plans from end-running the ACA's annual limitation requirements. We agree that plans should be held to the annual limits imposed at the beginning of the plan year, given that enrollees were provided this information at the initial time of enrollment through their summary of benefits and coverage (SBC). To allow non-calendar year plans to utilize the annual limits in place at the end of the plan year would be unfair to consumers who would have no idea what annual limits would be in effect at the time they enrolled in the plan.

Out-of-network services: HHS proposes to allow – but not require – issuers to count cost-sharing for out-of-network services towards the annual limitation on cost-sharing.

ACS CAN supports this proposed policy. Cancer patients often need to go out-of-network to access specialized providers necessary for their cancer treatment. While we support HHS' proposal, we also urge the Department to monitor the extent to which enrollees are utilizing out-of-network services, particularly for highly specialized services such as cancer care, as an indicator of the adequacy of the plan's network.

In addition, we are concerned that enrollees who utilize out-of-network services are subject to balance billing, which occurs when the out-of-network provider's costs exceed the issuer's in-network payment rate leaving the enrollee responsible for the difference (in addition to any cost-sharing required by the insurer). We urge HHS to adopt requirements that all QHPs protect consumers from balance billing when they are granted an exception to receive out-of-network services at in-network rates. We note that such requirements are already in place for multi-state plans.

Cost-sharing limitations: HHS proposes to clarify that the annual limitation on cost-sharing for self-only coverage would apply to all individuals, regardless of whether the individual is covered by an individual or family policy. In other words, an individual's cost-sharing for the EHB may never exceed the self-only limitation on cost-sharing.

ACS CAN supports HHS' proposal. The ACA intended to limit an individual's annual cost-sharing for covered items and services. This limit should be applied on an individual basis. Individuals should not be subject to higher annual limits simply due to their family size.

g. Minimum Value (§ 156.145)

The ACA requires that large employers offering employer-sponsored coverage must meet a "minimum value" (MV) threshold of covering at least 60 percent of expected costs. Earlier this year, HHS and Treasury released guidance indicating that in order to meet the MV threshold plans must provide substantial coverage of inpatient hospital and physician services. The proposed rule would promulgate this requirement.

ACS CAN supports the promulgation of the earlier guidance. Most individuals who are enrolled in employer-sponsored insurance would assume that their plan covers hospitalization when medically

necessary. Plans should not be permitted to skirt the intent of the ACA by offering coverage that fails to meet such critical services.

As HHS promulgates this requirement, we urge the Department to provide additional guidance in terms of what constitutes coverage of hospitalization services. We urge HHS to require that plans cover inpatient hospitalization for medically necessary services and are prohibited from imposing policies that create an undue burden or hinder access to medically necessary services (such as arbitrary caps on the number of days of inpatient hospitalization services).

In addition, we urge HHS to require that these plans cover emergency room services, medically necessary hospital outpatient services, as well as provide minimum prescription drug coverage. Given that these large group health plans are not subject to the ACA's essential health benefit requirements, we urge HHS to establish a benchmark to ensure that these plans provide minimum essential services to its employees.

U.S. Preventive Services Task Force Recommendations

As HHS finalizes changes to the essential benefits package, we urge the Department to provide additional clarification with respect to U.S. Preventive Services Task Force (USPSTF) recommendations. Under the ACA, plans are required to cover all recommendations that receive an "A" or "B" rating. We are concerned plans are providing inconsistent and less than comprehensive coverage for the ACA-required USPSTF recommendations[5] – particularly as they relate to cancer screenings (including lung cancer, skin cancer, cervical cancer, colorectal cancer, and breast cancer), BRCA risk assessment and genetic counseling, tobacco cessation, behavioral counseling, and weight loss counseling all of which are key components of cancer prevention. The USPSTF recommendations are for clinical practice and, as such, are not translated into insurance coverage benefits. Therefore these preventive services can vary by insurers based on individual interpretation of the USPSTF recommendation. This results in uneven coverage and confusion for both clinicians and consumers.

HHS has provided information to plans on some of the preventive services that should be covered to ensure compliance with the USPSTF "A" or "B" rated recommendations. For example, in May, the Department of Labor – in cooperation with HHS and Treasury – published a Frequently Asked Questions about the Affordable Care Act focused on plan's requirement to cover tobacco cessation interventions.[6]

While ACS CAN applauds release of this FAQ, we believe that in accordance with the ACA, HHS needs to clearly define the USPSTF recommendations as benefits that plans must cover. For example, the tobacco cessation FAQ requires plans to cover all Food and Drug Administration (FDA) approved tobacco cessation medications at no cost to the enrollee, but the FAQ is silent on whether the plan could charge a co-payment for an office visit for the enrollee to obtain the prescription.

We urge HHS to promulgate additional requirements further defining which specific services plans must cover in order to be compliant with this provision of the ACA. In addition, we urge HHS to monitor the extent to which plans are covering USPSTF recommended services that receive an "A" and "B" rating.

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[5] United States Preventive Services Task Force, USPSTF A and B Recommendations by Date, http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations-by-date/.

[6] Department of Labor, FAQs about Affordable Care Implementation (Part XIX), (May 2, 2014), available at http://www.dol.gov/ebsa/faqs/faq-aca19.html.

3. Qualified Health Plan Minimum Certification Standards

c. Network Adequacy Standards (§ 156.230)

HHS notes that the National Association of Insurance Commissioners (NAIC) is in the process of drafting a Model Act related to network adequacy and thus will wait until the conclusion of that multi-stakeholder process before proposing significant changes to the network adequacy rules. In the meantime, HHS proposes a limited number of changes to its network adequacy requirements.

ACS CAN appreciates HHS' recognition of the NAIC's work in crafting a network adequacy Model Act. We will be filing comments on the Model Act. We support the NAIC's transparent process for collecting stakeholder input. However, in order to the NAIC standards to apply, States will need to affirmatively enact the NAIC's Model Act – a process that can take time, depending on other state priorities. If all States do not enact the Model Act in a timely manner there may be uneven consumer protections among the various states. Thus, we urge HHS in future rulemaking to promulgate federal network adequacy standards, but allow states who wish to enact stronger state protections to do so.

Clarification of out-of-network providers: HHS proposes to specify that its network provider standards will only apply to in-network providers. Out-of-network providers may not be counted for purposes of meeting network adequacy requirements.

ACS CAN applauds HHS' clarification that plans can only count in-network providers for purposes of meeting HHS' network provider standards. However, we note that many plans use a tiered network for providers. The fact that consumers are subject to higher costs if they use providers in higher tiers essentially keeps these providers out of reach for many consumers. Therefore, we urge HHS to clarify that only in-network, first tiered providers will count in determining the adequacy of the plan's network.

Transitional period: HHS encourages – but does not require – issuers that use a network of providers to offer new enrollees transitional care for an ongoing course of treatment. HHS suggests that this transitional period begin with the enrollee's effective date of coverage and last for at least 29 days after (for a minimum of 30 days). This policy would apply to any services furnished by a provider (regardless of whether the provider is in the plan's network) as long as the enrollee received health service from that provider under an ongoing course of treatment in the 90 days prior to the effective date of coverage.

ACS CAN urges HHS to require – and not simply encourage – plans to provide a transitional period of coverage for individuals who are newly enrolled in a plan and are undergoing active treatment. Cancer patients rely on the expertise of a specialized provider (e.g., an oncologist, radiation oncologist, and surgeon) throughout their cancer journey (from point of diagnosis, through active treatment, to survivorship). Switching providers during the course of active treatment can disrupt a patient's care. For specialized diseases and conditions, like cancer, delayed care could significantly impede the treatment options and overall survival of the individual.

We urge HHS to create an additional safeguard so that individuals with serious medical conditions – like cancer – who are currently in active treatment should continue to have access to their provider throughout the course of treatment, regardless of whether the provider is included in the new plan's network. In such cases, the individual should incur no greater cost-sharing to access the provider under the new plan than would have been imposed under the prior plan.

Provider directory: HHS proposes issuers publish an up-to-date, accurate and complete provider directory, including information on which providers are accepting new patients, the provider's office location(s), contact information, specialty medical group, and any institutional affiliations. This information is to be available to current and prospective enrollees and must be updated at least monthly. If the issuer offers multiple networks, the general public should be easily able to discern which network is associated with which plan.

ACS CAN supports this proposal. Earlier this year, ACS CAN conducted an analysis to determine the extent to which cancer patients could obtain information regarding whether a plan contracted with a particular oncologist.[7] Our analysis revealed that in general plans provided coverage of oncologists, but that it was often difficult to determine the number and range of oncology-related providers included in a plan's network.

We urge HHS to provide a standardized format plans would be required to use so that the information can be compared across plan options and different issuers. The provider directory template needs to account for the different types of health plans and their delivery networks in a way that an average consumer can understand so that if, for example, an HMO uses a gatekeeper model for specialty referrals, this information is clearly explained so the consumer is not confused about the absence of specialists listed in the directory.

We support HHS' proposal that provider directories contain information regarding whether the provider is accepting new patients. To the extent that providers are only accepting new patients in certain locations, that information should be noted as well. We urge HHS to, at a minimum, take steps to verify the accuracy of the directories, even if only on a random sampling basis, and at licensing and re-certification.

We also urge HHS require plans to note the medical specialty, including subspecialty, of each provider and standardize this information. In our analysis, each issuer specifies the search terms for particular oncology subspecialties differently. For example, even with one national company, search terms to identify oncology specialists in the federal employees' health benefit product were sometimes different than those for a particular plan in the Marketplace. That difficulty is exacerbated for the consumer attempting to compare networks among different issuers in their community.

d. Essential Community Providers (§ 156.235)

HHS proposes a number of changes to strengthen essential community provider (ECP) standards. QHPs would be required to demonstrate a sufficient percentage (to be determined by HHS and specified in guidance) of available ECPs in the plan's service area for which it has contracts. HHS proposes to require that issuers offer contracts for participation in the plan to at least one ECP in each county area. The Preamble notes the "good faith" contact should offer "the same rates and contract provisions as other contracts accepted by or offered to similarly situated providers that are not ECPs." 79 Fed. Reg. at 70727. HHS will require that plans that fail to satisfy the ECP standard must provide a narrative justification describing how the provider network(s) offer an adequate level of service for individuals in low-income areas.

[7] American Cancer Society Cancer Action Network, Cancer Care and the Adequacy of Provider Networks Under the ACA Marketplace Plans, (June 2014), available at http://www.acscan.org/content/wp-content/uploads/2014/07/ACS-CAN-Cancer-providers-and-QHP-Networks.pdf.

While we appreciate HHS' intent to ensure that plans include ECPs in their plan networks, we have concerns with the policies proposed by HHS. Under the proposal, issuers must contract with at least one ECP in six categories of providers. The proposal includes children's hospitals and free-standing cancer centers in the "hospital" ECP category. We are concerned that lumping these providers within the same category places cancer patients at an unfair disadvantage. As a result, we are concerned that QHPs may not choose to contract with these providers, who often provide specialized cancer care. We are also concerned that QHPs are only required to make a good faith effort to contract with these vital providers. We urge HHS to monitor the extent to which children's hospitals and free-standing cancer centers – both of which can provide specialized cancer care to individuals with unique health care needs – are included in QHP networks.

Finally, we note that some states have chosen to expand their Medicaid program through private option waivers from CMS. In these cases States are choosing to enroll their Medicaid expansion population into QHPs. We urge HHS to pay particular attention to ECP provisions of QHP issuers in these States to ensure that low-income individuals have access to ECPs.

e. Health Plan Applications and Notices (§ 156.250)

HHS proposes to extend the current meaningful access requirements to apply to other types of plan information (beyond the application and notices) for people with disabilities or limited English proficiency.

ACS CAN supports HHS' proposal, which will require plans to ensure that important plan materials are made available to individuals with limited English proficiency. We urge HHS to adopt this standard for the 2016 plan year.

4. Health Insurance Issuer Responsibility With Respect to Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

c. Plan Variations (§ 156.420)

Under current rules group health plans and health insurance issuers are required to offer a written summary of benefits and coverage (SBC) for each benefit package offered to covered entities and individuals. However, there is no requirement that the SBC reflect a QHP with cost-sharing reductions applied. HHS proposes to require QHP issuers to provide SBCs that accurately reflect plan variations to ensure that individuals have access to accurate representations of cost-sharing responsibilities for all coverage options, including cost-sharing reduction plans.

ACS CAN strongly supports HHS' proposal. The SBC requirement was included in the ACA in order to provide consumers with an idea of what their cost-sharing may be under a given plan. Individuals who qualify for a cost-sharing reduction plan have reduced cost-sharing obligations, but the current SBC fails to adequately inform these individuals of their expected reduced cost-sharing obligations. We support the inclusion of this important plan disclosure.

d. Changes in Eligibility for Cost-Sharing Reductions (§ 156.425)

HHS proposes that if an individual's eligibility for a cost-sharing plan variation changes, a QHP must provide an SBC that accurately reflects the new plan variation once the QHP has been notified by the Exchange of the individuals' change in eligibility. HHS proposes plans would be required to provide the new SBC no later than 7 business days following the receipt of the notice.

ACS CAN supports HHS' proposal, which will provide individuals in cost sharing reduction plans with accurate information regarding their cost-sharing obligations. We urge HHS to clarify that plans must make a good faith effort to provide individuals receipt of the notice no later than 7 business days after an individual's change in eligibility.

5. Minimum Essential Coverage

a. Other Coverage That Qualifies as Minimum Essential Coverage (§ 156.602)

While most states have phased out their high-risk pools, HHS notes that some state high risk pools will continue through 2015 and beyond. HHS proposes to designate as meeting the minimum essential coverage (MEC) requirements any qualified high-risk pool that is currently existence.

State high-risk pools once served as a vital source of health insurance coverage for individuals – like cancer patients – who were denied health insurance coverage because of a pre-existing condition. For some individuals in Medicaid non-expansion states, qualifying state high-risk pools can provide a much needed safety net and one of the few remaining coverage options.

We do note that while some individuals have chosen to retain their coverage under their state high-risk pool, the Marketplace plan options often provide more comprehensive coverage with lower out-of-pocket costs (particularly for individuals who qualify for advance premium tax credits and/or cost-sharing reduction plans).

We believe that through plan year 2016, HHS should continue to designate qualified high-risk pools as meeting the MEC requirements. However, over time these state high-risk pools should be phased out once individuals enrolled in these high-risk pools are able to obtain comprehensive and affordable health insurance coverage through another means.

6. Enforcement Remedies in Federally-Facilitated Exchanges

a. Available remedies (§ 156.800)

In the first Program Integrity Rule, HHS established a good faith compliance policy for QHPs offering coverage in 2014. Specifically the Rule provides that HHS will not impose sanctions against a QHP issuer in a FFE if the QHP has made a good faith effort to comply with the applicable Exchange requirements. The Preamble notes that some QHP issuers experienced difficulties adapting to the guidance and new processes imposed by CMS. However, HHS proposes to continue to resolve most compliance issues through technical assistance and thus proposes extending the good faith compliance standard through the end of the calendar year 2015.

ACS CAN recognizes that the first year of implementation of the marketplace – as with any new product – involved certain challenges. We appreciate HHS' attempts to resolve these compliance issues through technical assistance. However, we are concerned that a good faith compliance effort may not be sufficient to ensure that plans are fully complying with all rules and regulations. Beginning in plan year 2016, we urge HHS to adopt more punitive standards if plans fail follow prescribed practices.

b. Plan suppression (§ 156.815)

In order to protect consumers' interests, HHS, for the 2014 plan year, identified situations that made it necessary to suppress certain QHPs from enrolling individuals in the plan. HHS proposes to define suppression which would temporarily prevent the QHP from enrolling individuals in the FFE. Grounds for suppression include: (1) if the QHP notifies HHS of its intent to withdraw from the FFE; (2) the QHP submits incomplete or inaccurate data to HHS; (3) the QHP is in the process of being decertified or is appealing a complete decertification; (4) the QHP issuer is the subject of a pending, ongoing, or final state regulatory or enforcement action or determination that could impact the issuer's ability to enroll consumers or otherwise relates to the issuer offering QHPs in the FFE; and, (5) one of the exceptions to guaranteed availability of coverage related to special rules for network plans or financial capacity limits applies.

ACS CAN supports HHS' definition of suppression and the grounds for suppression of a QHP in the FFE. In addition, we urge HHS also to prohibit any plan that has been suppressed from engaging in any marketing while under suppression.

7. Quality Standards

a. Quality Improvement Strategy (§ 156.1130)

The ACA requires each QHP to implement a quality improvement strategy (QIS), which is defined as a payment structure that provides increased reimbursement or other incentives to improve the health outcomes of plan enrollees, prevent hospital readmissions, improve patient safety and reduce medical errors, implement wellness and health promotion activities, and reduce health and health care disparities. HHS proposes that each QHP issuer participating in an Exchange for at least 2 years must implement and report information regarding a QIS, which includes a payment structure that provides increased reimbursement or other market-based incentives consistent with the guidelines to be developed by HHS. Beginning in 2016, a QHP issuer participating in the FFE for at least 2 years would submit a QIS implementation plan to HHS and the applicable Exchange for each QHP, followed by annual progress reports.

ACS CAN appreciates the Department's attention to quality improvement and its intent to develop Quality Improvement Strategy (QIS) standards. We agree with HHS that QIS standards should leverage existing initiatives and proven quality improvement strategy tools.

We urge the Department to develop and make available a uniform template for reporting QIS data for both FFMS and state marketplaces. We strongly support the Department's intent to require QHP issuers participating in the marketplace to attest to compliance with QIS standards, along with other QHP quality initiatives.

Conclusion

On behalf of the American Cancer Society Cancer Action Network we thank you for the opportunity to comment on the proposed rule. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org or 202-585-3261.

Sincerely,

Kirsten Sloan
Senior Policy Director
American Cancer Society Cancer Action Network