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December 21, 2015

The Honorable Sylvia Burwell
Secretary
Department of Health and Human Services
Attention: CMS-9937-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

**Re: CMS-9937-P –Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017**
80 Fed. Reg. 75488 (December 2, 2015)

Dear Secretary Burwell:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the 2017 Notice of Benefit and Payment Parameters proposed rule. 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. Our letter includes comments on specific proposals. However, there are a few provisions worth highlighting:

- *Medicare Notices*: ACS CAN applauds HHS for acknowledging the need to provide additional information to individuals who may not be aware of their Medicare eligibility. We strongly urge HHS to develop and disseminate clear information to educate individuals who may be potentially eligible for Medicare about how and when to transition from the marketplace to the Medicare program.
- *Standardized Plan Option Designs*: ACS CAN agrees with HHS that standardized benefit packages can be beneficial to individuals as they shop for health insurance coverage. However, we have concerns with some aspects of HHS' proposed plan standardization.
- *Network Adequacy*: ACS CAN applauds HHS for recognizing the need to strengthen the network adequacy standards beginning with the 2017 plan year. We strongly encourage HHS to move forward with strong network adequacy standards that can be used as a minimum consumer protection and, at the same time, allow states who wish to do so to enact even stronger protections.

**B. Part 146—Requirements for the Group Health Insurance Market**

*1. Guaranteed Availability of Coverage for Employers in the Small Group Market (§ 146.150)*

The guaranteed availability of coverage provisions of the Affordable Care Act (ACA) are some of the most important patient protections in health care reform. These provisions prohibit plans from denying coverage to qualified individuals, or (through the Small Business Health Options Program) to employers based on health status, pre-existing condition, or most other factors. HHS proposes to add an exception to this rule for a plan issuer who is in the process of discontinuing a plan product, or completely ceasing sale of plans in a marketplace or exchange. HHS proposes giving plan issuers who have announced they will be discontinuing a product an exception to the rule that they must accept new enrollees into that product. Plan issuers must give states and enrollees 90 days' notice when they intend to stop operating a plan product.

ACS CAN supports this proposal. Individuals with cancer need timely access to treatments and when that access is disrupted the effectiveness of the treatment could be jeopardized and the individual's chance of survival can be significantly reduced. It can be frustrating and disruptive to a patient in active cancer treatment to enroll in a plan only to have it cease existing in less than 90 days.

**D. Part 153 – Standards Related to Reinsurance, Risk Corridors and Risk Adjustment**

*2. Provisions and Parameters for the Permanent Risk Adjustment Program*

b. Proposed Updates to the Risk Adjustment Model (§153.320)

HHS proposes to continue to use the same risk adjustment methodology finalized in the 2014 Payment Notice, and proposes data updates similar to those proposed in the 2016 Payment Notice.

ACS CAN continues to support 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 into the model should boost issuers' confidence in the model's predictive power which, in turn, could reduce risk selection behaviors and help to stabilize premiums.

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

*2. General Standards Related to the Establishment of an Exchange*

b. Additional Required Benefits (§ 155.170)

Under the ACA, states requiring qualified health benefit plans (QHPs) to cover additional benefits beyond essential health benefits (EHBs) must make payments either to the enrollee or the issuer to defray the cost of those additional benefits. Current rules apply this requirement only to additional benefits enacted after December 31, 2011. The proposed rule seeks to clarify that this rule applies to state additional benefits provided through legislation, regulation, guidance, or other state action after January 1, 2012.

ACS CAN believes the inclusion of the EHB provisions are a vital component to ensure that QHPs provide robust coverage of products and services. However, we are concerned that by essentially freezing the additional benefits beyond the EHBs, states are hesitant to enact mandates that would provide access to necessary covered services. For example, since 2011, some states have attempted to enact policies that clarify that a follow-up colonoscopy following a positive fecal occult blood test (FOBT) test is a preventive benefit and thus should be provided to an enrollee with no cost-sharing. ACS CAN supports such proposals, which would increase the number of individuals who are screened for colon cancer. Unfortunately, state legislative efforts often are hampered because of the requirement that the state would bear the responsibility for defraying the cost of this additional benefit, even if a majority of issuers already offer the benefit.

We urge HHS to consider allowing states to enact legislation, regulation, guidance, or other state action to clarify that important preventive benefits and screenings should not count as an "additional benefit" and thus the state could mandate coverage for these preventive services without defraying the additional cost of these benefits.

*3. General Functions of an Exchange*

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

HHS proposes to amend the requirements for consumer assistance tools for state based exchanges (SBEs) that opt to use the federal platform. To avoid duplicating efforts, states using the federal platform will not be required to operate full call centers, but rather telephone hotlines to respond to requests for assistance from consumers in the state. These states will also be required to maintain an informational website that directs consumers to healthcare.gov.

ACS CAN appreciates HHS' intention to allow states to use resources more efficiently. However, the preamble fails to clarify the difference between a "call center" and a "telephone hotline." For example, it is unclear whether the former is required to be operated 24/7 by live customer-service operators whereas the latter can simply be an automatic service. When shopping for health care coverage consumers need 24/7 access to reliable, accurate information, including the ability to speak with a live operator who is knowledgeable and able to answer questions.

In addition, if the state-based website will simply exist to redirect individuals to healthcare.gov, it is imperative that both the state and HHS ensure that the links between the state website and healthcare.gov are fully functional. Broken links can be problematic to consumers shopping for health insurance coverage because they leave the individual vulnerable to obtaining incorrect information.

c. Standards Applicable to Navigators Under §§ 155.210 and 155.215; Standards Applicable to Consumer Assistance Tools and Programs of an Exchange Under § 155.205(d) and (e); and Standards Applicable to Non-Navigator Assistance Personnel in an FFE and to Non-Navigator Assistance Personnel Funded through an Exchange Establishment Grant (§§ 155.205, 155.210, and 155.215)

HHS proposes to require Navigators to provide targeted assistance to underserved and vulnerable populations. SBEs would define and identify these populations, while HHS will identify them for federally-facilitated exchanges (FFEs) through Navigator Funding Opportunity Announcements. These changes would apply beginning with the next set of Navigator grants awarded in 2018.

The number of uninsured Americans continues to drop as health insurance marketplaces and Medicaid expansion (where implemented) enter the third year. However, it increasingly is becoming difficult to further decrease the number of uninsured Americans, in large part because those who remain uninsured are the hardest to reach and/or the most reluctant to enroll. Targeted outreach strategies are needed. As the preamble notes, regulations already require Navigators to have expertise in the needs of underserved populations. ACS CAN supports taking a further step and requiring Navigators to use this expertise to target these populations. We also support allowing Exchanges – both FFEs and SBEs – to define their own vulnerable and underserved populations and potential FFE grantees to suggest populations, because these will differ from state to state and area to area.

*Additional Navigator topics*: HHS proposes to add the following additional topics to the post-enrollment assistance requirements for Navigators: (1) filing Exchange eligibility appeals; (2) understanding and applying for exemptions to the shared responsibility payment; (3) understanding the premium tax credit reconciliation process and IRS resources; and, (4) understanding basic health coverage concepts and how to use health coverage.

ACS CAN supports the addition of all these topics to Navigator requirements. Navigators are a natural place for consumers to receive this information, particularly if the consumer sees the same Navigator every year to enroll in health insurance coverage and develops a relationship.

*Tax information*: HHS requests comments on whether it should require Navigators to provide a disclosure stating they are not acting as tax advisors when giving consumers information about tax credits or IRS resources.

ACS CAN supports this proposal. While we strongly support the Navigator program, consumers should be made aware of the fact that Navigators are intended to provide information necessary to help an individual choose a health plan to best meet her needs. We support the proposal for Navigators to provide disclosures and urge HHS to ensure that this disclosure be written in consumer-friendly formats and should be designed so as not be too burdensome for Navigators.

*Basic health information*: ACS CAN strongly supports the proposal to require Navigators to provide consumers help with understanding basic health coverage concepts and how to use coverage. Only about half of Americans understand basic health insurance terms like premium, deductible and copay; and nearly nine out of ten adults have difficulty using health information to make informed decisions about their health.[1] Many individuals enrolled in marketplace plans – particularly those who may have been uninsured previously – are likely to have problems understanding their health coverage. By including this requirement for Navigators, HHS recognizes that enrolling patients in health coverage is only the first step in improving their health. The next step is getting patients to use their coverage – particularly primary care and preventive services.

If an enrollee has already established a relationship with a Navigator, potentially over multiple years, the Navigator is a natural place for the enrollee to go for advice on using her health coverage. Some Navigators already are imbedded in health systems and are well placed to provide this type of guidance. ACS CAN strongly supports this proposal, and concurs with the list of sample topics on understanding

[1] Alliance for Health Reform. "Health Literacy and Health Insurance Literacy: Do Consumers Know What They Are Buying?" January 6, 2015. Available at: http://www.allhealth.org/publications/Private_health_insurance/Health-Literacy-Toolkit_163.pdf.

health insurance included in the Notice. Some enrollees, like cancer patients, may need more specialized assistance than can be addressed by these general topics. We encourage HHS to provide Navigators training on how to help enrollees access more specialized assistance. Additionally, while we recognize HHS has limits on what it can require of non-Navigator assistance personnel and certified application counselors, we hope these entities also will consider providing assistance with understanding and using health insurance coverage. We encourage HHS to make training available to all types of enrollment assistors where appropriate.

*Training*: ACS CAN also supports HHS' proposal to require that any individual or entity carrying out consumer assistance functions complete training prior to performing those duties, including outreach and education activities. Navigators and similar individuals serve a vital role and assist consumers in making important choices. It is crucial that Navigators are properly trained so consumers are not misled about the health insurance they are buying and understand the costs they will be required to pay.

d. Ability of States to Permit Agents and Brokers to Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

HHS proposes new standards for terminating agent and broker agreements with FFEs based on fraudulent or abusive conduct. HHS also establishes standards of conduct for agents and brokers, including that they will: (1) provide consumers with correct information; (2) provide FFEs with correct information; (3) obtain consent of the individual employer or employee before assisting them; (4) protect personally identifiable information; and, (5) comply with all applicable federal and state laws and regulations.

ACS CAN is supportive of these new standards for providing correct information. It is important to prevent fraud and abuse so consumers feel confident in enrolling in health insurance through healthcare.gov, state exchanges, and other approved methods. When an agent or broker provides incorrect or fraudulent information to consumers or to FFEs, it can have serious impacts. For example, if the agent or broker provides the enrollee with incorrect information, the enrollee might not choose the plan that best meets her needs, or be surprised by bills she was not anticipating and cannot pay. Alternatively, if the agent or broker provides FFEs incorrect information about enrollee income, the enrollee can receive unexpected tax bills because she was not actually eligible for subsidies. We encourage HHS to maintain vigilant enforcement of these key provisions.

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

d. Medicare Notices

The preamble notes the importance of providing notification to enrollees who are enrolled in a QHP with information on their potential eligibility for Medicare. HHS seeks comment on whether and how to notify an enrollee of her Medicare eligibility. One potential option noted in the preamble is a "pop up" text on healthcare.gov for individuals who are turning 65 during the benefit year.

ACS CAN applauds HHS for acknowledging the need to provide additional information to individuals who may not be aware of their Medicare eligibility. People with marketplace coverage who could become Medicare eligible currently are not made aware of their Medicare eligibility. This creates problems for these individuals who often are unaware of their need to enroll in the Medicare program and to cancel their Marketplace plan. In fact, many of these individuals may only learn of their Medicare eligibility

when their access to premium tax credits terminates upon becoming eligible for Medicare. Individuals who do not enroll in Medicare when first eligible may face lifetime late enrollment penalties, could experience gaps in coverage, and could face tax penalties resulting from the loss of premium tax credits and delayed Medicare enrollment.

We strongly urge HHS to proactively notify and educate individuals who may be potentially eligible for Medicare about how and when to transition from the marketplace to the Medicare program. While we support the proposed "pop up" text for individuals who may be turning 65 in the benefit year, we do not believe this notification alone constitutes sufficient notification and education. We urge CMS to ensure that individuals who potentially may be eligible for Medicare receive notification in appropriate formats (which may include traditional mailings) outlining Medicare eligibility rules, including specific information regarding the consequences of remaining in the marketplace plan (e.g., loss of premium tax credits and potential consequences of delayed Medicare enrollment). HHS must ensure this information is provided to individuals regardless of whether they are enrolled in a state-based or federally-facilitated marketplace.

It should be noted that not all individuals who may be eligible for Medicare coverage should pursue enrollment in Medicare. For example, individuals with end-stage renal disease (ESRD) and those who are ineligible for premium free Medicare Part A may wish to consider retaining their marketplace coverage and choose not to enroll in the Medicare program.

The potential for consumer confusion further highlights the need for HHS to develop clear information and education targeted to specific populations. ASC CAN stands ready to work with HHS on the development of these specific tools.

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

a. Annual Eligibility Redetermination (§ 155.335(j))

Currently, enrollees who do not choose a new plan for themselves at the start of a new benefit year are automatically re-enrolled into the same or similar plan for the following year, based on a re-enrollment hierarchy established in the 2016 Notice of Benefit and Payment Parameters Final Rule. Under the 2016 rule, beneficiaries automatically are enrolled in the same plan. If that plan is not available, the enrollee automatically is enrolled in a plan at the same metal level if the enrollee's current plan (product) is not available. If a similar metal-level product is not available, the enrollee is enrolled in a plan one metal level higher or lower if no plan remains available at the same metal level. Failing those options, the enrollee would be enrolled in any other qualified health plan offered by the insurer through the exchange if no plan is available in an adjacent metal level.

HHS proposes to change this hierarchy to better protect consumers eligible for cost-sharing reductions who must remain in a silver-level plan to maintain cost-sharing reduction eligibility. Specifically, if such an enrollee's current silver-level QHP is not available and the enrollee's current product no longer includes a silver-level QHP available through the Exchange, the enrollee's coverage would be renewed in a silver–level QHP in the product offered by the same issuer that is most similar to the enrollee's current product, rather than in a plan one metal level higher or lower than his or current silver-level QHP, but within the same product. HHS also asks for comments on which factors should be used to determine which product is most similar to the consumer's current product.

ACS CAN recognizes the important goal re-enrollment hierarchies serve: keeping consumers insured and making it easy for them to re-enroll. This adjustment to the hierarchy is a reasonable way to protect consumers from losing eligibility for cost-sharing reductions – provided that the consumer receives adequate notice of her re-enrollment in a different product. This notice should be written for low literacy levels and be as clear as possible about the implications of the plan change, and how consumers can override automatic re-enrollment.

For an individual in active cancer treatment, the provider network and covered benefits are an important consideration. For cancer patients in active treatment, switching providers or facilities could cause major disruption to their treatment. In addition, levels of cost-sharing, particularly for drugs can be a critical component of a cancer patient's treatment. A change in plan that resulted in significantly increased out-of-pocket costs for oncology care would be incredibly disruptive and challenging for the patient in active treatment. We are concerned that auto-enrolling an individual into a similar plan offered by the same issuer does not guarantee the individual that the provider networks or plan formularies will be the same as the discontinued plan. Therefore, patients in active treatment for a serious illness who are auto-enrolled in a plan that significantly changes access to providers or medications involved in that treatment should be allowed a special enrollment period.[2]

*Hierarchies based on premiums*: HHS also asks for feedback on additional re-enrollment hierarchies, including hierarchies based primarily on premium costs. ACS CAN continues to be extremely concerned about such hierarchies. A patient who is enrolled in a plan with a lower premium might unknowingly incur higher cost-sharing and out of pocket costs. 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.[3] Auto-enrollment based solely on a lower cost plan could put a cancer patient at risk for significant out-of-pocket costs. We also note that default enrolling an individual into the lowest-premium plan could result in the individual having to switch health insurers, which may result in the individual experiencing 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.

*Auto-enrollment hierarchy election upon initial enrollment*: HHS seeks comments on whether consumers should be offered multiple re-enrollment hierarchies when first signing up for coverage through healthcare.gov. ACS CAN believes many consumers already are overwhelmed by options and decisions when enrolling in healthcare – adding the option of signing up for automatic re-enrollment for future years will contribute to an already confusing process. Most consumers who would be savvy enough to understand their options for hierarchies and choose wisely are more likely to be the consumers who likely do not need automatic re-enrollment. For all these reasons, ACS CAN continues to

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[2] In our comments on § 155.420, discussed in more detail below, ACS CAN recommends individuals who have been automatically enrolled in a plan that does not cover the benefits and services they need be eligible for a special enrollment period.

[3] ACS CAN encourages cancer patients to focus on other aspects of the plan – like cost-sharing, covered benefits and in-network providers – before focusing on the plan's premium. 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-the-Right-Health-Insurance-Plan-2015-FINAL.pdf (updated November 2015).

encourage HHS to not implement automatic re-enrollment hierarchies based primarily on premium costs, and not offer hierarchy options to consumers at enrollment.

c. Annual Open Enrollment Period (§ 155.410)

HHS proposes that for benefit year 2017, the annual open enrollment period be November 1, 2016 – January 31, 2017, which is consistent with the 2016 open enrollment period.

ACS CAN supports consistency in the annual open enrollment period to make it easier for consumers to understand and plan accordingly. However, having the open enrollment period extend past January 1st may confuse some consumers who do not realize that they have to enroll before December 15th in order to be covered under a plan by January 1st of the following year. This might result in unexpected gaps in coverage. We note that the Medicare annual election period begins on October 15th and ends December 7th each year, with coverage beginning January 1st of the following 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.

d. Special Enrollment Periods (§ 155.420)

ACS CAN recognizes that past regulations establish several Special Enrollment Periods (SEPs) that give patients in certain situations access to needed healthcare coverage. The American Cancer Society works with cancer patients throughout their treatment journey, and hears from many about problems obtaining quality health insurance coverage. Based on these experiences, we urge HHS to consider the following additional SEPs:

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 an SEP for individuals whose plan increases cost sharing or coverage for a prescription drug currently taken by the individual.[4] Currently, issuers are permitted to change their prescription drug formularies during the plan year. As a result, a cancer

[4] ACS CAN has long urged HHS to ensure that if plans make mid-year formulary changes, enrollees who currently are taking the affected prescription drug be permitted to continue to take that drug without having to undergo an appeals process throughout the remainder of the plan year. We note that such a requirement exists in the Medicare Part D program.

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 currently are 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.

SEP for patients auto-enrolled in a plan that does not meet their needs: Under current re-enrollment hierarchies and the changes proposed in this rule, if a patient's plan is discontinued they may be auto-enrolled into a plan that does not have the same provider network or formulary. This is a serious concern for patients currently undergoing cancer treatment, as well as other patients being treated for serious illness. We urge HHS to create an SEP for individuals who currently are in active treatment if the plan they have been auto-enrolled in significantly limits access to their current providers, facilities, or medications.

e. Termination of Coverage (§ 155.460)

Currently enrollees have the option to terminate their coverage in a QHP. HHS proposes to allow an enrollee to terminate coverage retroactively within 60 days of discovering unwanted enrollment under specific circumstances: (1) enrollment despite enrollee attempts to terminate coverage; (2) unintentional or erroneous enrollment because of mistakes on the part of the Exchange, HHS, or third parties; and, (3) fraudulent enrollment.

The right to terminate coverage is an important consumer protection, and ACS CAN supports these provisions. However, given that termination of coverage outside an open enrollment period could result in a gap in coverage, we urge HHS to provide individuals who terminate their coverage with notice written in consumer-friendly terms that provides the individual with information regarding the ramifications of disenrollment.

*6. Appeals of Eligibility Determinations for Exchange Participation and Insurance Affordability Programs*

a. General Eligibility Appeals Requirements (§ 155.505)

HHS proposes to clarify that applicants and enrollees have the right to appeal a determination of eligibility for an enrollment period. § 155.505(b)(1)(iii). This proposal would apply to appeals provided by both the HHS appeals entity and a State Exchange appeals entity. HHS also proposes to add a clarification that applicants and enrollees have the right to appeal any decision issued by a State Exchange appeals entity as well as their right to appeal a denial of a request to vacate a dismissal made by a State Exchange appeals entity.

ACS CAN applauds HHS for clarifying that an individual's right of appeal extends to a determination of eligibility for an enrollment period. Many individuals do not fully understand all the requirements of

when and how to enroll in a QHP. As a result, individuals may miss important enrollment deadlines. Individuals who are low-income or for whom English is not a primary language are particularly vulnerable to missing these key deadlines.

c. Appeal Requests (§ 155.520)

HHS proposes to require the appeals entity to allow an applicant or enrollee to demonstrate, within a reasonable timeframe, that an appeal should proceed because a delay was caused by exceptional circumstances. Determinations of what constitutes "exceptional circumstances" and "reasonable timeframe" would be left to the appeals entity.

ACS CAN supports this proposal. We believe this policy is necessary to ensure that individuals not be denied their critical appeals rights in cases where extenuating circumstances have caused them to miss appeal deadlines. While we see the value in allowing the appeals entity flexibility in determining what constitutes "exceptional circumstances" and "reasonable timeframe", we are concerned that, absent some additional guidance from HHS, there could be inconsistent standards applied from different appeals entities. Therefore we urge HHS to provide some additional clarification of these key terms and maintain oversight to ensure the appeals entities are utilizing these appeals options appropriately.

*9. Exchange Functions: Certification of Qualified Health Plans*

a. Certification Standards for QHPs (§ 155.1000)

1. Denial of Certification

HHS notes it is considering using its existing discretion to deny certifications for QHPs that meet minimum standards, but are not ultimately in the interests of qualified individuals or qualified employers. HHS interprets the "interest" standard to mean QHPs should provide quality coverage to consumers.

ACS CAN supports HHS' proposal to ensure that QHPs meet minimum quality standards in order to be certified to offer coverage. We agree that an issuer's financial insolvency or data errors related to QHP applications are important factors to consider in determining whether to certify a QHP. In addition, we encourage HHS to consider the number of complaints filed by consumers regarding plan coverage or provider access. This would be an important factor in determining the extent to which an issuer is meeting the required standard.

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

*1. Standard Options*

a. Standardized Option Definition (§ 156.20)

HHS proposes standardized plan options as a way to simplify the comparison of plan offerings within a metal level. Under HHS' proposal, plans would have standardized cost-sharing for a key set of EHBs that comprise a large percentage of the total allowable costs for an average enrollee. These standardized plans would only be available in the FFEs and could be offered by plans in 2017. HHS states that having standardized plan options will "simplify the consumer plan selection process."

ACS CAN applauds HHS for proposing policies that seek to address the challenges of individuals who may be overwhelmed with plan options when shopping for health insurance coverage in the exchanges. The

American Cancer Society's HIAS representatives often hear from individuals with cancer about how overwhelming it can be to choose among too many health insurance plans. Recognizing how important it can be for individuals with cancer and survivors to choose a health insurance plan that provides coverage for their unique needs ACS CAN developed a health plan worksheet that helps individuals compare health insurance plans.[5]

ASC CAN agrees with HHS that standardized benefit packages can be beneficial to individuals as they shop for health insurance coverage. As noted in the preamble, this standardization could allow individuals shopping for coverage to focus on other aspects of their health insurance plan such as plan provider networks, covered benefits, quality, and premiums. However, we are concerned about some aspects of HHS' proposed plan standardization, which we discuss in more detail below.

b. Standardized Option Design Principles

HHS proposes one standardized benefit design for a bronze, silver, and gold plan option as well as a standardized option for each cost-sharing reduction (CSR) plan variation. The preamble notes that HHS does not propose a platinum standardized option due to the small number of issuers who offer platinum plans. HHS proposes to encourage issuers to offer at least one standardized option at the silver plan level (along with the associated standardized silver CSR plan variations). HHS indicated it would propose standardized option changes annually.

While we agree that the standard option benefit design will need to change over time, we strongly urge HHS to minimize changes from year-to-year so that consumers to do not face significant benefit design changes from one year to the next. We also would encourage HHS to use its notice of proposed rulemaking authority – rather than sub-regulatory guidance – for major changes to the standard option benefit designs. This will ensure that all interested parties have an opportunity to review and comment on the proposed changes and for those comments to be made through an open and transparent process. HHS should utilize the sub-regulatory process sparingly.

c. General Features of the Standardized Options

The preamble notes that HHS designed the standardized options to be as similar as possible to the most popular 2015 FFE QHPs (based on enrollment) in a manner that would generally not raise premiums.

ACS CAN appreciates HHS' efforts to ensure that a standardized plan option is designed in such a manner as to not increase premiums. However, we caution that popularity of a particular plan option – particularly in the early years of any new program – may not be the best indicator of highest quality plan. Rather, individuals may have chosen a plan based on name recognition or factors other than the coverage or service offered by the plan. We would encourage HHS to consider carefully the coverage of products and services provided by a plan in designing a standardized benefit option.

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[5] American Cancer Society Cancer Action Network, Health Plan Worksheet: Know Your Coverage and Costs, available at http://www.acscan.org/content/wp-content/uploads/2014/12/Health-Plan-Worksheet-Know-Your-Coverage-and-Costs.pdf. In addition to this worksheet, ASC CAN has a number of other tip sheets and fact sheets to educate individuals with cancer and survivors about key considerations to use when choosing a health plan. More information about those materials are available at http://www.acscan.org/healthcare/learn.

i. Drug Formularies

HHS proposes that each standardized option would have four prescription drug tiers – generic, preferred brand, non-preferred brand, and specialty drug tiers. At the same time, HHS would allow issuers to offer additional lower-cost tiers if desired.

ACS CAN supports the standardization of the number of prescription drug tiers. If the stated objective of the standardization of plan offerings is to allow consumers to better compare plans across issuers, then having a standardized number of tiers would be concordant to that outcome.

At the same time, it seems antithetical to allow issuers the option to add additional tiers to the number required by the standard option. If HHS intends to offer standardized plans then it stands to reason that a key component of the plan design is a fixed number of tiers in the prescription drug formulary.

ACS CAN urges HHS to adopt a five tier structure (with no option for additional tiers), with the first tier covering drugs that are available at no cost-sharing to the enrollee and the remaining four tiers to be as proposed by HHS. This will provide greater transparency to consumers regarding the plan's coverage for no-cost prescription drugs covered under the preventive services benefit such as tobacco cessation drugs. Plans may also add other drugs to this no cost-sharing tier to make the plan attractive to consumers.

We strongly urge HHS to define the parameters of each prescription drug tier. We note that the Medicare Part D program specifically defines what constitutes a specialty drug (currently the Part D plan specialty threshold is set at $600). No such threshold exists for QHPs and as a result, an issuer has no limit on the drugs it can place on the highest tier. This lack of clarity regarding what constitutes a specialty drug raises a number of anti-discrimination concerns. For example, in 2014, an Administrative Complaint was filed with the HHS Office of Civil Rights after it was discovered that several QHPs in Florida were imposing inordinate high cost-sharing for medications used in the treatment of HIV and AIDS.[6]

ii. Provider Tiers

HHS proposes that standardized plan options have no more than one in-network provider tier. The preamble notes that only 14 percent of FFE enrollees currently are enrolled in QHPs with more than one in-network tier.

ACS CAN appreciates HHS' intent to simplify the plan design for consumers. However, we are concerned with the lack of clarity regarding the number of physician tiers issuers would be permitted to use. For example, it is not clear whether a standard option plan could have multiple physician tiers – primary care physician, specialist, subspecialist, non-preferred specialist – all with different levels of cost-sharing. We urge HHS to provide further clarification on this issue of what constitutes a provider tier and the extent to which plans are limited in the categories of provider tiers.

[6] AIDS Institute and NHeLP Administrative Complaint dated May 29, 2014, available at http://www.healthlaw.org/issues/disability-rights/HHS-HIV-Complaint#.VmnasvlViGI.

iii. Deductible-Exempt Services

HHS proposes to exempt from the deductible certain routine services such as primary care, specialist visits (at the silver and gold metal levels), and generic drugs. This policy is designed to ensure that "access to coverage translates into access to care for routine and chronic conditions" and that enrollees receive "some up-front value for their premium dollars." 80 Fed. Reg. at 75543.

ACS CAN appreciates HHS' intent, which is to encourage individuals to obtain high-value health care services and not be impeded by the plan's deductible. Preventive services are a critical component of primary care, particularly for cancer. Half of all cancers are preventable. We note that under the ACA, preventive services that receive an "A" or "B" rating from the U.S. Preventive Services Task Force (USPSTF) are required to be provided at no cost-sharing.

Research has shown that cost can be a barrier to individuals obtaining access to necessary cancer screenings and other preventive services. While the ACA has required that individuals have access to certain cancer screenings and other preventive services at no cost, there remains a lack of clarity regarding the extent to which an enrollee would receive follow-up screenings at no cost. For example, under practice guidelines an individual whose fecal occult blood test (FOBT) is positive should receive additional screenings – usually a follow-up colonoscopy – to determine if the initial test was a true- or false-positive. It is not clear whether plans are covering this second screening as a preventive service and thus do not impose cost-sharing on the enrollee. ACS CAN has long advocated that any additional cancer screening up to the point of diagnosis should be considered a preventive service and should be provided at no cost-sharing to the enrollee. However, until HHS provides this clarification at the very least these follow-up services should be provided pre-deductible.

In addition, numerous studies have demonstrated the link between cancer and physical inactivity, unhealthy eating habits, and excess weight.[7] To the extent that a plan provides coverage for nutrition counseling, physical activity, and weight management beyond the preventive services required by the USPSTF, we would urge that these services be provided to an enrollee pre-deductible.

Individuals who have successfully completed their cancer treatments will need to receive follow-up care from their oncologist to ensure the treatment continues to be successful and to prevent the recurrence of cancer. The length of follow up care varies depending on the type of cancer and the individual. ACS CAN urges HHS to clarify that follow-up oncology visits (including any medically necessary laboratory or diagnostic testing) should be provided to the individual pre-deductible.

iv. Copayment vs. Coinsurance

ACS CAN applauds HHS for acknowledging that consumers prefer copayments to coinsurance because copayments are more transparent to the consumer and make it easier to predict out-of-pocket costs. Plan designs using coinsurance are not transparent. Coinsurance makes it impossible for an individual to determine her expected out-of-pocket costs because the cost of the drug is not provided to the individual. The ability to predict and plan for costs is very important for individuals with cancer and those with chronic conditions, particularly patients who are low-income and very price-sensitive. Because of this, plan designs including coinsurance prevent patients from adequately comparing plans.

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[7] Kushi LH, Doyle C, McCullough M, et al. and the American Cancer Society 2010 Nutrition and Physical Activity Guidelines Advisory Committee. American Cancer Society Guidelines on Nutrition and Physical Activity for Cancer Prevention. *CA Cancer J Clin* 2012;62:30-67.

We urge HHS to consider prohibiting the use of coinsurance in its standardized plan option, or lowering the coinsurance percentages. At the very least, if a plan is permitted to use coinsurance, HHS should require the plan to provide an estimate of out-of-pocket costs associated with all drugs covered using coinsurance.

d. Specific Standardized Option Designs

*Coinsurance vs. copayment*: As stated above, if the intended purpose of the standardization of plan designs is to allow individuals better opportunity to compare plan options, we question why plans would be permitted to use coinsurance in the specialty drug tier. Coinsurance is not transparent to consumers. At the very least, if HHS insists on permitting plans to use coinsurance for the highest tier, we strongly urge HHS to require that plans create some sort of out-of-pocket cost calculator – similar to what has been in use for the Medicare Part D program since 2006 – to provide consumers with an estimate of their anticipated out-of-pocket prescription drug costs.

*Medical vs. prescription drug benefit*: We note that it can be challenging for individuals to obtain information regarding their health plan's coverage of prescription drugs provided under the medical – not prescription drug – benefit. In a 2015 white paper,[8] ACS CAN analyzed coverage of cancer drugs in silver plan formularies in six states – California, Florida, Illinois, North Carolina, Texas, and Washington – to determine the extent to which these plans covered the cancer drugs and the extent to which plan coverage was transparent to the consumer. Our analysis determined that it was often challenging to determine from the plan websites whether they provided coverage for physician-administered IV medications, making it difficult for patients using these drugs to choose an appropriate health plan for their needs. We urge HHS to require that plans list the cost-sharing associated with physician-administered drugs, regardless of whether the drug is covered under the medical or prescription drug benefit.

*Geographic variation*: HHS does not propose to vary the standardized options by state or region. ASC CAN supports this proposal and notes that the Medicare Part D standard benefit does not vary by geographic region.

*4. Essential Health Benefits Package*

a. Prescription Drug Benefits (§ 156.122)

HHS does not propose any changes to the prescription drug benefits, but requests comments on policies it may adopt in the future.

*Exceptions process*: Currently the exceptions process allows an enrollee (or their designee or physician) to request and gain access to clinically appropriate drugs that are not covered by the plan. In cases where the enrollee seeks a drug that is covered under the plan but is denied to the enrollee, the enrollee must appeal the denial of coverage through the appeals process – a separate process from the exceptions process. Some state laws require the appeals process to be used for denials of non-formulary drugs. HHS is considering establishing that in a state with coverage appeals laws or

[8] American Cancer Society Cancer Action Network, ACS CAN Examination of Cancer Drug Coverage and Transparency in the Health Insurance Marketplace, Washington, DC: American Cancer Society Cancer Action Network; November 2015, available at: http://www.acscan.org/content/wp-content/uploads/2015/11/ACS%20CAN%20Drug%20Formulary%20Paper%20FINAL.pdf.

regulations that more stringent than (or in conflict with) the federal exceptions process, the state's coverage appeals process would apply.

ACS CAN is concerned with the potential impact of this proposal. Recent HHS formulary exception external review requirements provide that a standard exception request is required to be completed within 72 hours and external review of an expedited request is required to be completed within 48 hours.[9] While we believe that a state law that provides greater consumer protection should be permitted, we note there are few states that provide greater consumer protections and note the timelines recently promulgated by HHS are consistent with other federal programs.

State laws that are inconsistent with these timeframes should not take precedent. To do so would be to undermine important consumer protections. Under HHS' proposal, if a state law is in conflict with the federal requirement – even if the federal requirement provides more stringent consumer protections – the state law would apply. Under this proposal, a cancer patient in a state with less stringent exceptions laws could wait potentially months for a determination on whether a particular chemotherapy treatment would be approved by the plan. In cancer care, delay of necessary treatments can negatively impact a patient's prognosis. We strongly encourage HHS to ensure that individuals have access to an exceptions process that is at least as stringent as the recently promulgated federal standard.

*Second level of internal review*: HHS also is considering whether to amend the exceptions process to incorporate a second level of internal review. This second level of review would be subject to the same timelines as the first level of review.

ACS CAN questions whether a second level of internal review is necessary. The preamble offers no policy rationale supporting this requirement. We are concerned this additional level would serve as a delay in an individual's access to medically necessary products or services.

*5. Qualified Health Plan Minimum Certification Standards*

a. Network Adequacy Standards (§ 156.230)

ACS CAN applauds HHS for recognizing the need to strengthen the network adequacy standards beginning with the 2017 plan year. Recently the National Association of Insurance Commissioners (NAIC) adopted the Health Benefit Plan Network Access and Adequacy Model Act. While there are some improvements to be made, on the whole ACS CAN is pleased with the Model Act which, if enacted by a state, will vastly improve an individual's access to providers within her plan's network. It is not yet clear how many states will adopt the Model Act. Therefore, we strongly encourage HHS to move forward with strong network adequacy standards that can be used as a minimum consumer protection and at the same time allow states who wish to do so enact even stronger protections.

i. State Selection of Minimum Network Adequacy Standards

HHS proposes that FFEs would rely on State reviews for network adequacy in States in which an FFE is operating, provided that HHS determined that the State uses an acceptable quantifiable network adequacy metric. HHS would discuss with States their selection in advance of the start of the certification cycle to determine whether the State's network adequacy standard would be acceptable

[9] 45 C.F.R. § 156.122(c)(1)(ii) promulgated as part of the 2016 Notice of Benefit and Payment Parameters rule. Department Health and Human Services, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 Fed. Reg. 10750 (February 27, 2015).

and would notify issuers via sub-regulatory guidance whether the State or Federal default standards would apply. In States that do not select a network adequacy standard, the FFE would conduct an independent review using the Federal default standard. HHS intends to detail the specific criteria and process for meeting the standard in the annual Letter to Issuers, including specific metrics such as prospective time and distance standards, minimum provider ratios, and other minimum standards.

*Quantitative standards*: ACS CAN applauds HHS for proposing specific quantitative standards to determine the adequacy of a plan's network. We support HHS' proposal to use prospective time standards calculated at the county level beginning in plan year 2017. The preamble notes that HHS proposes to use standards similar to the Medicare Advantage (MA) standards. We note that the MA program also requires the use of minimum provider and facility ratios and we encourage HHS to include these requirements as part of their minimum time and distance standards. We note that the MA standards will need to be modified to include populations and services not served by the Medicare population (e.g., children and dental services).

Quantitative standards are imperative to ensure that individuals have access to the covered benefits provided pursuant to their plan. These standards should be applied to all QHPs – not just those in FFE states. We note that a number of SBEs do not currently utilize quantitative standards in their network adequacy standards.

*Prior approval*: It is imperative that the FFE or the SBE review and approve the plan's provider network prior to the product being sold on the exchange. Such prior approval – using previously established quantitative standards – will help to ensure that access problems are addressed in advance of the product being sold and utilized by consumers.

*Hospital-based physicians*: As part of its network adequacy standards, we strongly encourage HHS to pay particular attention to the number of hospital-based physicians at in-network hospitals who are included in in a QHP's network. Many consumers incorrectly assume that when they go to an in-network hospital all the physicians within that hospital are included in the plan's network. Unfortunately this is not always the case – particularly for certain specialties such as anesthesiologists, emergency department physicians, and radiologists – and can expose consumers to balance billing.[10]

*Tiered networks*: Increasingly more plans are utilizing a tiered network structure. As HHS – and SBEs – conduct their network adequacy determinations, we strongly encourage clarification that only those providers who are included in the lowest-cost provider tier would count for purposes of determining the adequacy of the plan's network. Issuers that wish to provide products with multi-tiered providers should be permitted to do so. However, a consumer should be able to access all covered benefits through providers in the lowest cost-sharing tier without unreasonable travel or delay.

*Sub-regulatory guidance*: ACS CAN appreciates HHS' desire for flexibility. However, we are concerned with the proposal to further define the network adequacy standards through sub-regulatory guidance, in the form of the Letter to Issuers. Given the importance of these standards, we believe that HHS should instead provide this information through a more formal rulemaking process. This will ensure that all stakeholders have an opportunity to comment on these standards. We are concerned that sub-regulatory guidance can be altered at any time with minimal opportunity for public comment.

[10] We use the term "balance billing" to mean the difference between the provider's charge and the allowed amount under a plan. This definition is in line with that provided by healthcare.gov.

ii. Additional Network Adequacy Standards

HHS proposes to require QHP issuers in all FFEs to notify enrollees when a provider leaves the network – regardless of whether the provider is being removed by choice. HHS proposes to require that a QHP in an FFE make a good faith effort to provide written notice to all enrollees who are regular patients of the provider, or who receive primary care services from the provider, that the provider is leaving the network. HHS also proposes to require the issuer, in cases where the provider terminated without cause, to allow an enrollee in active treatment to continue treatment until the treatment is complete or for 90 days, whichever is shorter, at in-network cost-sharing rates.

ACS CAN applauds HHS for recognizing the need to ensure that policies will provide continuity of care in instances where a provider leaves a plan's network mid-year. Individuals with cancer need timely access to treatments and when that access is disrupted the effectiveness of the treatment could be jeopardized and the individual's chance of survival can be significantly reduced.

*Notification of mid-year provider changes*: ACS CAN supports the requirement that QHPs provide advance written notice when a provider leaves the plan's network mid-year. We urge HHS to specify that QHPs provide notice to all enrollees of the departing physician.

In addition, we note that in certain specialties – like oncology – it can be particularly important for individuals to know if their provider leaves their plan's network. Many individuals battling cancer and cancer survivors develop a special relationship with their oncologist. Therefore we urge HHS to require that if an oncologist leaves a plan's network mid-year, the QHP must notify all enrollees who received services from that oncologist.

*Continuity of Care*: We applaud HHS for proposing to require the issuer to allow an enrollee in active treatment to continue treatment at in-network cost-sharing rates. However, we strongly urge HHS to amend the length of time for this much-needed continuity of care. Under the proposed rule, this continuity of care would extend until the treatment is complete or for 90 days, whichever is shorter. For an individual battling cancer, the 90 day period may be insufficient to cover the full course of treatment. In such instances the cancer patient would have to find another provider mid-treatment which could negatively impact her timely access to treatment and could disrupt the effectiveness of the treatments. Thus, we urge HHS to require that individuals in an active course of treatment should be permitted to continue treatment at in-network cost-sharing rates until the treatment is complete.

*Definition of "active course of treatment"*: HHS proposes to use the NAIC's Network Adequacy Model Act's definition of "active course of treatment".[11] We note that while the preamble to the proposed rule further defines the terms "life-threatening health condition" and "serious acute condition" as defined by the NAIC Network Adequacy Model Act, the proposed regulation does not include these definitions. Both the NAIC's definition and the proposed rule's preamble would define a serious acute condition "as a disease or condition requiring complex on-going care which the covered person is currently receiving, such as chemotherapy, post-operative fists, or radiation therapy." These services are an imperative component of cancer treatment and should be expressly provided for within the text of regulation's definition of "active course of treatment" – not just as part of the preamble – as the NAIC has done.

[11] National Association of Insurance Commissioners, Health Benefit Plan Network Access and Adequacy Model Act, Nov. 2015, section 6(L)(2)(a).

*Appeals*: We applaud HHS for expressly requiring that requests for continuity of care be subject to the health benefit plan's internal and external grievance and appeal processes. We note the NAIC Model Act contains such a provision.

*State standards*: We also note that some states may have stronger consumer protections for continuity of care. We urge HHS to clarify that the federal standards constitute a floor. If a state enacts stronger continuity of care provisions, the QHPs should be required to use the more stringent state standard.

*Out-of-Network Cost sharing*: We appreciate HHS' inclusion of policies designed to address surprise medical billing (or "balance billing") which often occurs when an individual receives services from an out-of-network provider at an in-network facility (often without the knowledge or control of the consumer). A recent survey by *Consumer Reports* found that 30 percent of privately insured Americans have received a bill where their plan paid much less than they anticipated.[12] We are concerned that the provisions proposed by HHS fall short of protecting consumers from these surprise medical bills, as discussed in more detail below.

*Cost-sharing*: HHS proposes to require QHPs to count towards the annual cost sharing limit the amount of cost sharing paid by an enrollee for an essential health benefit provided by an out-of-network provider in an in-network setting. We are concerned that this provision fails to provide the consumer protection against balance billing. HHS' definition of cost sharing expressly excludes balance billing.[13] Thus, any balance bill would not count towards the enrollee's maximum out-of-pocket limit. In addition, we note that a majority of QHPs do not provide out-of-network coverage and thus services provided by an out-of-network provider would constitute non-covered services and thus would not be included under the definition of cost-sharing. We urge HHS to clarify that balance billing amounts and cost-sharing amounts for essential health benefits must be counted towards the enrollee's maximum out-of-pocket limit, even if the QHP does not otherwise cover out-of-network care.

*Written notice*: Under the proposed definition, the limited cost-sharing benefit discussed above would not apply if the QHP provides a written notice to the enrollee at least 10 business days before the provision of the benefit that additional costs may be incurred.

Written notice can be helpful to consumers only if it provides meaningful information – and is not simply a "form notice" – including a reasonable estimate of the projected amounts for which the enrollee may be responsible for the specific procedure or condition for which they are being admitted. The notice also must contain a list of in-network providers who may be available to the enrollee. But even advance notice is insufficient to protect consumers from unfair charges over which they have little or no control. We support the NAIC Network Adequacy Model Act requirement that consumers pay only their in-network cost-sharing and are held financially harmless for charges in excess of $500.[14]

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[12] Consumer Reports National Research Center, "Surprise Medical Bills Survey," May 2015, available at http://consumersunion.org/wp-content/uploads/2015/05/CY-2015-SURPRISE-MEDICAL-BILLS-SURVEY-REPORT-PUBLIC.pdf.

[13] Under current HHS regulations, the term "cost sharing" means "any expenditure required by or on behalf of an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services." 45 C.F.R. § 155.20.

[14] National Association of Insurance Commissioners, Health Benefit Plan Network Access and Adequacy Model Act, Nov. 2015, section 7(D).

*Emergency situations*: We urge HHS to provide greater protection to consumers in emergency situations, when they often have no control over the facility or provider who treats them. While under the proposed rule, issuers are required to charge in-network cost-sharing rates for emergency services performed at out-of-network facilities, there is no requirement that consumers be protected from balance billing in emergency situations. We strongly urge HHS to prohibit balance billing in emergency circumstances.

*Rating of QHP relative network coverage*: The preamble notes that HHS is considering including on healthcare.gov a rating of each QHP's relative network coverage. ACS CAN supports this proposal which can help consumers identify plans that provide a greater breadth of coverage. We caution, however, that a single rating may be insufficient. We encourage HHS to explore a rating system similar to Hospital Compare,[15] which allows a consumer to obtain rating information on different aspects of care and services provided by the hospital. Consumers shopping for health insurance coverage have different needs. A cancer patient, for example, would want to know the breadth of a plan's network with respect to oncology care and, depending on her cancer, the use of specialized cancer centers or children's hospitals. We recognize that developing this tool will take time and urge HHS to seek input from all stakeholders – including consumer organizations – when designing and developing the methodology for the tool.

*New patients*: In the preamble HHS solicits comments on whether an issuer should be required to survey all of its contracted providers on a regular basis to determine if a sufficient number of network providers are accepting new patients. ACS CAN strongly supports this proposal. If a provider is with the plan's network, but isn't taking new patients, for practical purposes the provider is not available to that new patient. We also encourage HHS to require that issuers use this survey to verify the accuracy of their provider directories.

*Tiered networks*: In the preamble HHS solicits comments on the transparency of issuers' standards for selecting and tiering participating providers for FFE QHPs as well as whether issuers should be required to make available to HHS, and the State upon request, selecting and tiering criteria. ACS CAN supports this proposal. Absent oversight, issuers are permitted to describe their plans using terms like "high value" or "high performing" without disclosing the criteria to determine the value or performance of the plan. In essence, these terms that should reflect the measurable quality of the plan design are in practice being used as marketing terms that can be misleading to a consumer.

b. Essential Community Providers (§ 156.235)

QHPs are required to include a certain number of Essential Community Providers (ECPs) in their networks. Currently, an ECP location is counted as one ECP regardless of how many full-time practitioners are at that location. HHS proposes to count multiple contracted full-time equivalent ECP practitioners practicing in a single location as separate ECPs starting in plan years beginning after January 1, 2018.

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[15] Hospital Compare allows consumers to select multiple hospitals and directly compare performance measure information related to heart attack, heart failure, pneumonia, surgery and other conditions. These results are organized by: (1) Patient Survey Results; (2) Timely and Effective Care; (3) Readmissions, Complications, and Deaths; (4) Use of Medical Imaging; (5) Linking Quality to Payment; and, (6) Medicare Volume. Hospital Compare is available at www.hospitalcompare.hhs.gov.

*Number of ECP providers*: ACS CAN has concerns about the proposal. We recognize the logic in this proposal – an ECP-designated clinic that has 5 doctors on staff can certainly serve more patients than a clinic with one doctor on staff. However, availability of doctors is not the only element of providing true access to healthcare. Other factors such as geography are important in determining access to health care services. For example, if the closest clinic is an hour away from a patient's home and that patient is not able travel to the clinic (either because she is not able to take leave from her employment in order to visit the clinic during clinic hours or is unable to find transportation) the clinic is inaccessible for reasons that have little to do with the number of providers at the clinic. The purpose of the ECP provisions is to ensure that individuals have access to an adequate distribution of doctors within their reach. Therefore, we urge HHS to consider using a formula that not only accounts for multiple ECP practitioners at one site, but also accounts for geographic distribution of ECPs.

*Disaggregation of ECP categories*: Additionally, ACS CAN is very disappointed that HHS chose to not disaggregate ECP categories as it suggested it planned to do for the 2017 plan year. Currently, children's hospital centers and free-standing cancer centers fall into the ECP category of hospitals. Children's hospitals and free-standing cancer centers provide specialized oncology services not available at all hospitals. We are concerned that by aggregating children's hospitals and free-standing cancer clinics into the hospital category, there is a disincentive for plans to contract with these specialized facilities.

For example, recently the American Cancer Society's HIAS call center has been contacted by numerous cancer patients in active treatment who are unable to find any plans in the Texas marketplace that include the University of Texas MD Anderson Cancer Center in the network.[16] Patients who rely on the specialized services offered at MD Anderson have few options. These patients could enroll in a marketplace plan that does not contract with MD Anderson, but then would have to pay the entire cost of treatment, which can be tens of thousands of dollars. In these cases, the patients' out-of-pocket costs likely would not count towards their out-of-pocket maximum unless the plan provided some coverage for out-of-network care. Alternatively, these patients could find a plan outside of the marketplace, but an individual who qualifies for an advance premium tax credit or CSR plan would forfeit these subsidies by going outside the marketplace. Further, there is no guarantee that a non-marketplace plan would contract with MD Anderson. ACS CAN does not consider any of these scenarios acceptable or good healthcare policy. We strongly urge HHS to move forward with its previous plan to disaggregate ECP categories.

g. Other Considerations

In the preamble, HHS reminds issuers that QHPs are subject to other federal civil rights laws with respect to non-discrimination requirements.

ACS CAN appreciates HHS' reminder of the need to ensure that plans do not discriminate against individuals. We note that HHS has not yet issued a final rule implementing section 1557 of the ACA. The non-discrimination proposed rule is an important first step towards ensuring that health benefit designs cannot discriminate against patients in ways that deny them access to critical care. We urge HHS to promulgate the final rule as soon as possible.

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[16] Diaz, Joy, and Emily Donahue. "NO OBAMACARE PLANS COVER TREATMENT AT HOUSTON'S TOP CANCER CENTER." *Texas Standard* 3 Nov. 2015, available at http://www.texasstandard.org/stories/cancer-patients-will-be-left-out-of-next-years-obamacare-plans/.

As we mentioned in our comments on the non-discrimination proposed rule,[17] additional non-discrimination guidance is imperative to help guarantee that patients with serious medical conditions will have access to the providers, services, and medications they need. Specifically in promulgating the final rule, we urge HHS to address the following issues:

- *Illustrative Examples*: We strongly urge HHS to provide specific examples in the final regulation of benefit design features that could be deemed discriminatory under the ACA.
- *Formulary Design*: As HHS noted in the 2016 Notice of Benefit and Payment Parameters proposed rule, placing all drugs to treat a disease or condition on the highest formulary tier could constitute a discriminatory benefit design. We urge HHS to promulgate final regulations prohibiting this practice.
- *Formulary Switching*: We note that Medicare Part D protects a beneficiary who is taking a particular drug by prohibiting Part D issuers from amending the plan's formulary mid-year for that individual. No such protection exists in the small group or individual marketplace. Thus, it is possible that a plan could offer a formulary to prospective enrollees and then significantly change the formulary mid-year, thereby essentially denying coverage for drugs to treat a specific disease or condition. We strongly urge the Department to clarify that mid-year formulary changes will be subject to strict scrutiny to determine whether the formulary change could be discriminatory in nature.
- *Narrow Networks*: We urge the Department to prohibit plans from designing their networks in such a manner that excludes and/or severely limits providers who treat individuals with serious and chronic conditions such as cancer.
- *Utilization Management*: We note that some plans employ excessive utilization management tools (such as prior authorization, step therapy, etc.) in ways that may impede appropriate timely access. When used properly, these tools can be beneficial. However, these tools also have the potential to be utilized in a punitive manner when directed at a specific population. We urge the Department to clarify that unreasonable utilization management can constitute a discriminatory practice and thus would not be permitted.

*9. Qualified Health Plan Issuer Responsibilities*

d. Other Notices (§ 156.1256)

HHS proposes to require that issuers, in the case of a plan or benefit display error, notify their enrollees within 30 calendar days after the error is identified, if directed to do so by the FFE. In such cases issuers would be required to notify their enrollees of the error and inform them of their eligibility for a special enrollment period.

ACS CAN strongly supports this proposal. We urge HHS to further clarify what constitutes a plan or benefit display error. For example, it is not clear from the preamble whether errors in the plan's provider directory or formulary would be sufficient to warrant such notice. Many individuals with

[17] Letter from Chris Hansen, President, American Cancer Society Cancer Action Network, to Sylvia Burwell, Secretary, Department of Health and Human Services (Nov. 9. 2015), available at http://www.acscan.org/content/wp-content/uploads/2015/12/ACS%20CAN%20Comments%20on%20Nondiscrimination%20Reg%20FINAL.pdf.

cancer choose a health plan based on the providers included in the plan's directory as well as the drugs covered under the plan's formulary. We urge HHS to clarify that errors found in either the plan's directory or formulary are sufficient to warrant notice to be provided to enrollees as well as a special enrollment period.

**H. Part 158 – Issuer Use of Premium Revenue: Reporting and Rebate Requirements**

*2. Reporting of Incurred Claims (§§ 158.103 and 158.140(a))*

HHS seeks comments on whether it should modify the treatment of a health insurance issuer's investments in fraud prevention activities for medical loss ratio (MLR) reporting purposes. HHS notes it is considering amending the MLR regulation to permit the counting of a health insurance issuer's investments in fraud prevention activities among those expenses attributable to incurred claims.

ACS CAN strongly opposes this policy. The ACA charged the NAIC with developing the MLR methodology. During the deliberations the NAIC had extensive discussion about the extent to which fraud prevention activities should be counted in the MLR calculation. Ultimately the NAIC determined that a quality improvement expense would include the cost of issuer's fraud recovery activities only up to the amount of fraudulent claims recovered. HHS included these requirements in its regulations implementing the MLR requirements.

We believe HHS should not modify its treatment of fraud prevention expenses at this time. The current requirements appropriately incentivize issuers to invest in these efforts. Permitting issuers to count all fraud prevention activities – beyond what is provided for in the current MLR requirements – would weaken the intent of the MLR requirements, which are to help ensure that consumers realize full value of their health care premiums.

Further, we note that the NAIC has created an MLR Quality Improvement Activities Subgroup that has been charged with reviewing new quality improvement initiatives and making recommendations to the HHS on whether additional changes are warranted. At the NAIC winter meeting, the Subgroup held a hearing to receive input on whether changes are needed. Subgroup members were skeptical of industry claims that fraud prevention activities should count as a quality improvement activity and requested the industry to provide more specific examples and justification for why the current requirements should be changed.[18] Industry comments are due to the Subgroup by January 15, 2016.

In light of the fact that the NAIC's process is ongoing and the fact that to date no compelling rationale has been provided warranting the change to the fraud prevention activities, we urge HHS to refrain from adopting any changes to the MLR requirements as part of its final rule. Given that ACA mandated the NAIC to develop the MLR methodology, we urge HHS to delay changes unless and until such recommendations have been made by the NAIC.

[18] Hansard, Sara. "State Regulators Wary of Insurer Requests on Medical Loss Ratio." *BNA Health Care Daily Report*, Nov. 23, 2015. Available online at: http://www.bna.com/state-regulators-wary-n57982063849/.

**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