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September 28, 2011

Donald M. Berwick, M.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9989-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: CMS-9989-P, "Establishment of Exchanges and Qualified Health Plans"

Dear Dr. Berwick:

The National Health Council (NHC) appreciates the opportunity to submit comments on the proposed rule implementing Affordable Insurance Exchanges ("Exchanges"), consistent with Title I of the Affordable Care Act (ACA), CMS-9989-P, "Establishment of Exchanges and Qualified Health Plans." Specifically, the NHC submits comments on three important questions posed in the proposed rule.

The NHC is the only organization of its kind that brings together all segments of the health care community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 100 national health-related organizations and businesses, its core membership includes approximately 50 of the nation's leading patient advocacy groups, which control its governance. Other members include professional societies and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical, medical device, biotechnology, and insurance companies. We look forward to working with CMS as it finalizes this rule.

First, we believe that at least one of the two types of entities serving as Navigators should be a community and consumer-focused nonprofit organization. Exchanges must be designed in a way that improves accessibility, affordability, and quality of care for patients. The NHC strongly believes that the involvement of community and consumer-focused nonprofit organizations is critical to ensure that these objectives are met. A patient-focused entity to help enrollees navigate the Exchange is vital to achieving the goals of health care reform.

Second, the NHC believes that Navigators should be operational on the first day of the open enrollment period for Qualified Health Plans (QHPs) in the Exchanges. Early engagement with the Navigator program is critical so that patients can make informed decisions when selecting among several coverage options and other services. Without early access to a Navigator, patients most eager to obtain coverage will be left unassisted as they struggle to make important decisions about their health care. Below are additional details on our perspective.

Finally, the NHC strongly urges CMS to establish federal minimum network adequacy standards with which all Exchanges must comply. We believe this is the only way to ensure that every Exchange meets the ACA's directive to "ensure that the provider network of each [Qualified Health Plan (QHP)] offers a sufficient choice of providers for enrollees."

At Least One Navigator Should Be Operated By a Patient-Centered Nonprofit

In section 155.210 of the proposed rule, CMS proposes standards for the Navigator program. Among the specific considerations cited is the question of whether CMS should require that at least one of the two types of entities serving as Navigators include a community and consumer-focused nonprofit organization, or whether CMS should require that Navigator grantees reflect a cross section of stakeholders. For the reasons stated below, the NHC urges CMS to require at least one consumer-focused nonprofit entity.

The NHC supports and commends CMS for placing requirements on Exchanges to ensure patient engagement throughout an Exchange's operations. The success of an Exchange depends not only on what types of health insurance products and services are available to patients, but also the extent to which these products and services are accessible to the patients that need them. Exchanges must equip patients with the tools they need in order to successfully engage in and contribute to the new health insurance marketplace. Without a Navigator, patients will often misunderstand the benefits and cost-sharing mechanisms of plans and may choose a plan that is not appropriate or affordable for them. We support the inclusion of patient outreach and assistance services as outlined in the proposed rule, and we urge CMS to include them in the final rule. The NHC is greatly concerned, however, that without a patient-centered, nonprofit Navigator option, these services will not effectively reach patients that need them the most.

When Exchanges open for enrollment in 2013, patients with chronic diseases and disabilities will require meaningful guidance and education in order to choose the coverage that best suits their needs. Extensive outreach will also be important to reach patients who are homebound or who otherwise lack regular access to the health care system and to the typical channels of public communication. The NHC firmly believes that a patient-focused, nonprofit entity is best suited to carry out these functions in a manner that puts patients first. Well-established nonprofits will have a particular advantage, with proven track records and ability to both identify and find those in the greatest need. These organizations also tend to maintain networks of individuals that will be crucial for a successful outreach strategy.

Moreover, patients should have an option they can trust to address their unique needs as individuals. In addition to inspiring trust, the NHC believes that nonprofit entities will serve as the best option for Navigators because nonprofit organizations operate through boards and staffs, which can be structured to minimize conflicts of interest within the organization.

Therefore, the NHC strongly supports the proposed requirement that at least one Navigator program in each state be run by a patient-focused, nonprofit entity to ensure that the Exchange's functions are appropriately tailored to the unique needs and circumstances of the individual patient.

The Navigator Program Should Be Up and Running on Day One of Open Enrollment

In addition, the NHC supports CMS' proposal to require Navigator programs to be operational and accessible on the first day of the initial open enrollment period. The NHC agrees that patients will require substantial assistance in order to understand health insurance options and make informed choices. Accordingly, the relevant grants and training grantees must be awarded within a timeframe that allows for Navigators to be up and running on the first day that patients need them, if not before. To delay the availability of Navigator services beyond the first day of open enrollment will deny a critical access point for patients, especially those unable to use the Exchange independently due to debilitating chronic diseases, disabilities, cognitive impairments, and low health literacy.

The NHC's own work on exchanges suggests that plan design could differ substantially, even within an actuarial value level (i.e., platinum, gold, silver, and bronze). Further, plans offered by different insurers are likely to cover different sets of benefits, have different cost-sharing structure, and utilize different limits on certain benefits. All of these variables will further complicate the process for patients to select a plan that is most appropriate for their needs. To avoid confusion and ensure that patients select the proper plan, Navigators must be operational throughout the entire initial open enrollment period.

Congress designed the Exchange with a goal to increase health insurance coverage for all Americans. The NHC urges CMS to fulfill this objective by creating an Exchange that is truly accessible to all patients who require its services. To do otherwise would be a disservice both to patients and to the intent of the ACA. We encourage CMS to draw upon lessons learned from successful programs such as State Health Insurance Assistance Programs (SHIPs), which have proven to be invaluable for patients navigating federal health programs. Consumer-focused nonprofits and patient-volunteers have played an important role in expanding the reach of SHIPs by partnering with them to address the needs of individuals with specific diseases or disabilities through outreach and counseling.¹ Importantly, these programs are available for those who need them on an ongoing basis and during the entirety of the Medicare open enrollment periods.

In addition to these comments, we urge CMS to reference the NHC's policy recommendations outlined in our recent release titled "A United Patient Voice on Essential Health Benefits," which we have attached with this submission. The policy brief and model regulatory language included in this document address the important role that Navigators play to ensure transparency and quality in patient care.

¹ MedPac, "Report to Congress: Medicare Payment Policy." March, 2008.

Exchanges Must Ensure that Provider Networks Offer Sufficient Choice for Enrollees

Finally, the NHC supports CMS' proposal to require Exchanges to "ensure that the provider network of each [Qualified Health Plan (QHP)] offers a sufficient choice of providers for enrollees." The ACA requires the HHS Secretary to establish network adequacy requirements for health insurance issuers seeking certification as QHPs. However, the rule proposes to delegate this responsibility to each Exchange. The NHC strongly believes that CMS should establish in the final rule national standards that will serve as a minimum level of protection for network adequacy across the country. Such standards should be broad enough to accommodate each individual state's needs, but should also ensure that the enrollees of QHPs have a sufficient choice of primary care, specialty care, and tertiary care providers, as well as meaningful, timely, and affordable access to needed services.

In finalizing this rule, the NHC urges CMS to reference existing network adequacy models such as the Medicare Advantage Network Adequacy Criteria, which we used to develop our own model regulations. The NHC's model regulations on network adequacy can also be found in the attached document, "A United Patient Voice on Essential Health Benefits."

Thank you for this opportunity to share our comments. The NHC supports your efforts to ensure that Exchanges improve access to affordable health care for all patients. Please do not hesitate to contact Eric Gascho, NHC's Associate Director of Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org. You may also reach me on my direct, private line at 202-973-0546 or via e-mail at mweinberg@nhcouncil.org.

Sincerely,

A handwritten signature in black ink that reads "Myrl Weinberg". The signature is fluid and cursive, with a large, stylized "W" and a long, sweeping underline.

Myrl Weinberg, FASAE, CAE
President



A United Patient Voice on Essential Health Benefits

August 2011

Executive Summary

The Affordable Care Act offers limited guidance about the essential health benefits (EHB) package, the minimum standard benefit design for private health insurance coverage.¹ As the Center for Consumer Information and Insurance Oversight (CCIIO) finalizes the federal regulations establishing EHB policy, the National Health Council (NHC) offers its perspective that the regulations should define not only a fair and balanced benefit but also strong patient protections for the millions of people with chronic diseases and disabilities and their family caregivers who will rely on EHB policies.

To understand the process of developing a benefits package, the NHC commissioned an actuarial analysis to examine the cost of a comprehensive health benefits package, using the Blue Cross Blue Shield Standard Option (BCBS-SO) plan under the Federal Employee Health Benefits Plan as a model.² Rather than taking a piecemeal service-by-service approach, we focused on systemic safeguards to ensure a robust, affordable benefit. In brief, the analysis shows that benefit design (i.e., the cost-sharing structure), even within an actuarial value category, can differ considerably. Further, the analysis indicates that patient protections are critical to the success of qualified health plans and Exchanges and to the health needs of people who will rely on the EHB package.

The NHC envisions three levels of support into which comprehensive patient protections in EHB fall. The first level of patient protections within the EHB regulation would achieve a balance of cost and quality. This level of protection for patients involves the design of plans' benefit structures to avoid discrimination, encourage equal access, and provide clear guidance for plan members. The second level of patient protections in the EHB regulation would provide adequate supports for patient care and decision making. The third level of patient protections in the EHB regulation would ensure access to care through the use of tools of enforcement both for individuals as well as federal and state governments. For EHB and qualified health plans to operate as intended, the federal government must supervise states as they oversee plans operating in their states at the same time that individuals should hold their plans accountable for coverage policies.

As a voice for the patient community, the NHC is committed to ensuring adequate patient protections, as the ACA is implemented. As CCIIO finalizes the EHB package, the NHC strongly encourages the agency to include comprehensive patient protections in the regulation. This letter offers a logical framework to build these protections. For each level within the framework, the NHC offers, specific recommendations, rationale, and regulatory language to support the agency in developing the EHB package.

While the NHC's recommendations in this letter build the case for specific patient protections to be included in the EHB regulations that will safeguard people as they enroll in and navigate qualified health plans, they do not address specific services or the categories of services included in essential health benefits. Rather, this letter articulates a regulatory approach to ensure patient protections for a robust and affordable health care benefit.

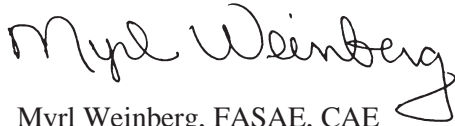
The NHC's unique perspective as a voice for the many people with chronic diseases and disabilities has led to the NHC's interest in the successful establishment and implementation of the EHB package. The

¹ The Affordable Care Act is the combination of the Patient Protection and Affordable Care Act (PPACA), P.L. 111-148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (HCERA), P.L. 111-152, enacted on March 30, 2010.

² Actuarial analysis performed by Actuarial Research Corporation and Avalere Health

NHC believes that broad patient protections are critical to the success of qualified health plans and Exchanges. As CCIIO finalizes the establishment of the essential health benefits, the NHC strongly encourages the agency to include in its regulations the continuum of patient protections supported in this letter.

Sincerely,

A handwritten signature in black ink that reads "Myrl Weinberg". The signature is fluid and cursive, with the first name "Myrl" and last name "Weinberg" clearly distinguishable.

Myrl Weinberg, FASAE, CAE
President
National Health Council

Background

For the past several years, the National Health Council (NHC) has been actively engaged in setting priorities for patients with chronic conditions to guide policymakers' approach to health reform. A central goal of health care reform is to ensure individuals have access to affordable and adequate insurance. To attain adequacy in insurance coverage, the Affordable Care Act of 2010 (ACA) requires the Secretary of Health and Human Services (HHS) to establish an essential health benefits package—a minimum standard for benefits that all qualified health plans and other non-grandfathered small and individual insurance plans must cover by 2014.

One of NHC's health reform priorities is to ensure that the essential health benefits (EHB) package provides access to affordable and adequate coverage. ACA presents the first time the federal government will establish a minimum standard benefit package for private health insurance coverage. However, the ACA offers only general guidance about how HHS should define the benefit package. More specific details surrounding EHB policy are expected in federal regulations to be released later this year. NHC believes that its unique voice offers a valuable perspective for HHS to consider as the Department writes and finalizes these federal regulations.

The NHC is the only organization of its kind that brings together all segments of the health care community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 100 national health-related organizations and businesses, its core membership includes approximately 50 of the nation's leading patient advocacy groups, which control its governance. Other members include professional societies and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical, medical device, biotechnology, and insurance companies.

Actuarial Analysis Uncovers Importance of Patient Cost Protections

The ACA offers broad guidelines to establish an EHB package that all qualified health plans must cover by 2014.³ In addition, all individual and small group plans (regardless of whether they meet the qualified health plan definition) must cover the essential benefits package. In general, the scope of benefits within the EHB must be equal to the scope of benefits provided under a typical employer plan. More specifically, the ACA identifies ten categories of services that must, at a minimum, be included in the EHB package. The ACA also creates restrictions on out-of-pocket spending in qualified health plans. The cost sharing may not exceed the cost sharing for Health Savings Accounts.⁴ For the small group market, deductibles may not exceed \$2,000 for individuals and \$4,000 for families. Out-of-pocket maximums are indexed by the percentage increase in average per capita premiums.⁵

The NHC believes that existing employer-sponsored insurance benefits, such as the Federal Employee Health Benefits Plan (FEHBP), may inform the process that the Secretary is taking to develop the benefits package. For this reason, the NHC commissioned an actuarial analysis to examine the cost of a comprehensive health benefits package, using an often mentioned benchmark standard for adequate coverage—the Blue Cross Blue Shield Standard Option (BCBS-SO) plan offered under the FEHBP.

³ A "qualified health plan" is a health plan that is certified by each exchange through which the plan is offered; provides the essential benefits package; is offered by an issuer that is licensed and in good standing in each state in which the plan is offered; agrees to offer at least one qualified plan in the silver and gold levels; agrees to charge the same premium whether the plan is sold through the exchange or outside the exchange; and complies with other requirements developed by the Secretary and the exchange. Section 1301, *Affordable Care Act of 2010*.

⁴ For 2011, maximum out-of-pocket costs for HSAs are \$5,950 for individual coverage and \$11,900 for family coverage.

⁵ The amount is increased by twice the percentage increase in average per capita premiums for family coverage.

The actuarial analysis estimated the cost to pay for covered expenses using 2011 National Health Accounts projections. Using standard administrative expenses and other assumptions, the estimated annual premium for this model plan would be approximately \$5,000 for an individual or nearly \$12,500 for a family. As it exists, the actuarial value of this model plan is 0.87, which is near the platinum level of coverage. The final step of the analysis adjusted the out-of-pocket costs for this model plan to accommodate the four actuarial levels established by the ACA—Platinum at 90 percent; Gold at 80 percent; Silver at 70 percent; and Bronze at 60 percent.

The results of the analysis also show that benefit design, even within an actuarial value category, can vary substantially. The ACA establishes out-of-pocket spending protections that do help protect people from excessively high costs. Even with these spending safeguards, there likely will be a great deal of variation in terms of cost-sharing for plans, especially at the beginning of each benefit year. For this reason, it will be critical for patients to enroll in plans that work with their health care usage patterns. For example, a person with a chronic condition may consider a plan with a lower out-of-pocket limit, even if the deductible or other early out-of-pocket spending is higher than other plans. For these reasons, the NHC has determined that affordability is a key protection for patients who will rely on EHB as a standard for coverage.

The NHC focuses its efforts on bringing attention to the needs of patients with chronic disease. Several studies have shown that out-of-pocket spending for people with chronic conditions is often thousands of dollars each year. For people with limited income and resources, even if they qualify for Exchange subsidies, the cost of enrolling in a qualified health plan may be higher than they can afford. Several studies have recently examined the “affordability” of potential plans in state Exchanges. The NHC’s analysis examined this issue as well to gain insight to the unique needs of high-cost enrollees. Figure 1 illustrates one scenario examined in this analysis.

Figure 1. At 250% FPL, a Family of Four with One Person with Kidney Disease May Struggle, Even with Subsidies

Annual Income (Gross)	\$55,875	
Median Necessities* (at 71%)	–\$39,671	Subtract the cost of taxes, child care, food, housing, transportation, and miscellaneous expenses of 10%
	\$16,204	
Maximum Premiums**	–\$4,438	Subtract the ACA-defined maximum premium a family at 250% FPL can pay (compared to ~\$8,000 for a silver plan with no subsidy)
	\$11,766	
OOP Maximum***	–\$5,950	Subtract the reduced out-of-pocket maximum due to 250% FPL (compared to \$11,900 with no subsidy)
	\$5,816	
Per Month	12	Divide by 12 for a estimate of remaining funds in monthly budget
	~\$485	

* The median percentage of a budget assigned to necessities was estimated by Gruber and Perry, April 2011.

** The ACA sets threshold levels for maximum premiums, above which people will receive subsidies. At 250% FPL, the maximum premium is 8.05% of income.

*** The ACA sets reduced out-of-pocket maximums for people with limited income. A Rand study estimated total out-of-pocket spending related to kidney disease was nearly \$9,000 in 2004.

The example above illustrates an average family of four living at 250 percent of the federal poverty level (FPL) in an area of the country with average cost of living. For people with limited income and high-cost health needs requiring significant out-of-pocket spending, health insurance coverage may still not be affordable, even with subsidies. In fact, a Commonwealth Fund report measuring affordability estimates that around 26 percent of people in this situation will not have room in their budgets to pay for health care. For those living in higher cost areas, median necessities would likely comprise a larger portion of a family's income. The report estimates that, for those at 250 percent of FPL in an area with high cost of living and high cost medical needs, 31.4 percent cannot afford to pay for necessities, health insurance premiums, and out-of-pocket costs, even with subsidies. This compares to 20.5 percent of people living in areas with low cost of living.⁶

Affordability is one critical element for patients with chronic health needs. The specific services each plan covers is another critical element. Health insurance plans likely will differ, not only by cost structure, but also by services covered, limits placed on coverage, provider networks, and other plan rules. This variety will offer an opportunity for people to enroll in coverage that meets their health care needs as well as the limits of their budgets. At the same time, the variety likely will mean that plan selection will be vital to people enrolling in qualified health plans, especially those with high cost health needs.

The actuarial analysis commissioned by NHC indicates that patient protections are critical to the success of qualified health plans and Exchanges and to the health needs of people who will rely on EHB. Further, the ACA requires the Secretary, in defining the benefits, to:

- ensure that such essential health benefits reflect an appropriate balance among the categories described above, so that benefits are not unduly weighted toward any category;
- not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life;
- take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups; and
- ensure that health benefits established as essential not be subject to denial to individuals against their wishes on the basis of the individuals' age or expected length of life or of the individuals' present or predicted disability, degree of medical dependency, or quality of life.

These parameters establish a clear role for the agency to address patient protections in drafting the regulations on EHB.

While the NHC's recommendations in this letter build the case for specific patient protections to be included in the EHB regulations that will safeguard people as they enroll in and navigate qualified health plans, they do not address specific services or the categories of services included in essential health benefits. Rather, this letter articulates a regulatory approach to ensure patient protections for a robust and affordable health care benefit.

⁶ Gruber J and I Perry. *Will the Affordable Care Act Make Health Insurance Affordable?* The Commonwealth Fund, 2011.

Defining the Essential Health Benefits

Much of the debate surrounding EHB to date has centered on the concept of essential. The definition of essential will set the foundation for how all services will be evaluated. Similar concepts such as *medical necessity* and *reasonable and necessary* are inadequately defined today and could serve as potential starting points for defining essential. The NHC recognizes the challenge of establishing a standard benefit package that is adequate across the spectrum of patient needs while remaining affordable for those who will need health insurance coverage.

Therefore, the NHC cautions HHS against establishing a rigid definition of the term and defining an inflexible set of specific services within the ten ACA-defined categories. The NHC's analysis of this matter and thorough understanding of the needs of patients have resulted in the conclusion that HHS and states must have adequate oversight of plans to ensure they are acting in the best interest of their members.

Levels of Patient Protections

The NHC envisions that patient protections in EHB fall into three levels of support. The first level of protections involves plan benefit structure to ensure coverage is high quality and non-discriminatory. Patient and consumer supports for care and decision-making fall into the second level of protections for patients. The final level is comprised of mechanisms of oversight, including methods for individuals to hold their plans accountable as well as oversight by state and federal government.

Level 1. Balancing Cost and Quality

The first objective of the EHB regulation should be to achieve a balance of cost and quality. This level of protection for patients involves the design of plans' benefit structures to avoid discrimination, encourage equal access, and provide clear guidance for plan members. Three specific patient protections should be included in the EHB regulation to help achieve this goal.

Cost-Sharing Protections

First, though the ACA requires EHB to reflect an appropriate balance among the ten categories of health services, additional protections are necessary to accomplish broad cost-sharing protections. The ACA leaves much flexibility to states to ensure plan compliance. Therefore, HHS has an obligation to ensure that states are performing oversight activities as required. Further, patients need to understand potential costs prior to enrollment and renewal, including in-network and out-of-network cost differentials.

As HHS reviews plan benefit designs and assesses access to care issues for enrollees, the agency may consider additional requirements on plans. For example, the Maryland Comprehensive Standard Health Benefit Plan specifies cost-sharing requirements for certain services and includes some service limits to offer an extra level of patient protection for enrollees in these plans.⁷ Specifically, the plan requires a \$100 copayment for emergency room services; a \$40 copayment for skilled nursing facility care; and service limits on outpatient rehabilitation services of 30 visits each for physical therapy, speech therapy, and occupational therapy.⁸

Cost-sharing protections should include:

- Requirements for plans to disclose to all prospective and current members the deductible, co-payment and co-insurance amounts applicable to in-network and out-of-network covered services

⁷ Maryland Comprehensive Standard Health Benefit Plan provides guaranteed access to a set of health benefits and cost-sharing arrangements that all carriers must offer to all small employers in Maryland.

⁸ http://mhcc.maryland.gov/smallgroup/cshbp_brochure.htm

- Oversight mechanisms to ensure that states are reviewing plan benefit design to determine that cost-sharing is neither unfair nor discriminatory

Continuity of Care Protections

Second, the EHB regulation should require plan cooperation and coordination when people switch enrollment between plans or between coverage (e.g., Medicaid and Exchange coverage). Patients, especially those with chronic conditions, may spend a considerable amount of time following plan rules working with their providers to tailor their treatment approach to best fit their needs and health status. Once people are stabilized on appropriate therapies and protocols, it is critical to minimize disruption to the often delicate balance of their treatment. Although some plans will honor previous care pathways and protect the continuity of care for their new members, there are no requirements for them to do so. Additionally, plans will often require new members to re-establish the medical necessity of their current course of treatment in order to comply with the plan's utilization management program and coverage policies.

As HHS assesses access to care issues, the agency may consider additional requirements for plan continuity. For example, HHS may consider options similar to the Part D Low-Income Subsidy (LIS) program. LIS offers auto and facilitated enrollment policies that ensure access to reduced cost Part D plans for Medicare beneficiaries with limited means. The Medicare Part D program also includes transition rules for plan enrollees to ensure that beneficiaries who are stabilized on a medication are not left without coverage. This transition covers enrollees throughout their Part D enrollment—upon initial Part D enrollment, at any changes of enrollment, as well as during annual changes to formularies between plan years.

Continuity of care protections should include:

- Protections for patients switching enrollment between qualified health plans or to or from Medicaid, so patients do not have to re-establish the necessity of treatment protocols already in place
- Navigator education programs that must provide information about the potential implications of switching between plans

Non-Discriminatory Plan Design

Third, the EHB regulation should provide for oversight of plan benefit design to avoid discrimination caused by unfair utilization management (UM) techniques or other plan design elements. The ACA specifically permits health plans to employ commonly used UM techniques; but at the same time, it prohibits plans from designing benefits that are discriminatory. Health plans often require UM tools, including fail first, prior authorization, step therapy, and other approaches. Health plans sometimes require members to try less expensive services, therapies, or prescription drugs prior to receiving coverage for more expensive options. In many cases, people with chronic conditions use expensive therapies and are subject to these UM techniques.

To ensure non-discriminatory utilization management, the regulation should include:

- Specific oversight mechanisms for states to use in reviewing plan UM policies to ensure practices are neither unfair nor discriminatory
- Requirements for plans to disclose to all prospective and current members all utilization management techniques as well as all limits on services
- Federal monitoring programs to ensure appropriate checks are in place to guarantee that plans are meeting federal requirements

Addressing these three priority areas will help plans achieve balance between costs and quality for members to help them avoid issues accessing health care services from their plans.

Level 2. Establishing Patient and Consumer Supports

The second objective of the EHB regulation should be to provide adequate support for patients as they receive health care services and make decisions about their care. Two particular protections should be included in the regulation to help achieve this goal.

Care Coordination and Management Requirements

First, the EHB regulation should require proven effective care coordination and management practices to improve outcomes and reduce total health care costs. A lack of care coordination contributes to problems within the health care system, including fragmented care, cost inefficiency, and poor outcomes. This is notable in particular for people with chronic conditions. The National Quality Forum defines care coordination as “a function that helps ensure that the patient’s needs and preferences for health services and information sharing across people, functions, and sites are met over time. Coordination maximizes the value of services delivered to patients by facilitating beneficial, efficient, safe, and high-quality patient experiences and improved health care outcomes.”⁹ Providers are often not reimbursed for care coordination, so there are limited incentives to engage in these activities.

Effective care coordination and management practices should include:

- Flexibility for plans to develop innovative strategies to compensate providers for effective care coordination
- Encouragement for state IT programs to include information about the care coordination policies of plans on state Exchange websites

State Navigator Programs

Second, the EHB regulation should contain specific requirements for state Navigator programs to assist patients in identifying appropriate plans for enrollment as well as navigating the enrollment and other key plan process. Even with the EHB service categories clearly defined, plans will still have some coverage and cost variations. For this reason, it will be critical for patients, especially those with multiple chronic conditions, to be able to identify the plan that best meets their specific needs. The state-based Navigator programs required by the ACA will provide some assistance for eligible individuals. However, it is unlikely these programs will have the capacity to assist everyone. Protections must be written into EHB regulation to provide further security to patients and consumers throughout the plan cycle—from pre-enrollment through delivery of benefits during the plan year.

The State Health Insurance Assistance Programs (SHIPs) are an often cited example of what a Navigator program could resemble. SHIPs provide assistance to Medicare beneficiaries and help them navigate their Medicare benefits.

Effective Navigator programs should include:

- Assistance with all aspects of plan processes, from selecting a plan to accessing health care benefits during the plan year
- Requirements to educate individuals of their plan rights, whether they have public or private insurance

⁹ http://www.qualityforum.org/projects/care_coordination.aspx

- Coordination with other consumer assistance programs in the state to ensure that assistance is available to as wide a population as feasible

Level 3. Requiring Mechanisms to Ensure Access

The third objective of the EHB regulation should be to ensure access through tools of enforcement both for individuals as well as federal and state governments. For EHB and qualified health plans to operate as intended, HHS must supervise states as they oversee plans operating in their states at the same time that individuals should hold their plans accountable for coverage policies. Two particular protections should be included in the EHB regulation to help achieve this goal.

Medical Necessity and Appeals and Grievances Processes

First, the EHB regulation should outline clear, understandable standards for plan medical necessity determinations. Additionally, the regulation should include clear and straightforward processes for members to file grievances with their plans and to appeal adverse plan coverage determinations. Successful navigation of health coverage often requires members and their providers to understand the standards that plans use in making medical necessity determinations, as well as how to appeal adverse decisions. EHB regulations should clarify and simplify these processes to make it easier for patients and providers to actively participate in health plan decisions. Without adequate protections, patients with complex health needs, including and especially those with chronic health conditions, may find it difficult to obtain coverage for certain health services. Finally, a clear grievance process gives plan members a voice to bring to light their concerns and ask their plans to change.

As HHS assesses the tools of enforcement for individuals enrolled in qualified health plans, the agency may consider other models currently in place. For instance, Medicare Part D offers an example of a federally regulated, nationwide program that has set requirements of participating plans. The plans must describe for patients in detail the exceptions and appeals processes, and must utilize a standardized grievance process.

Clear processes for medical necessity determinations as well as appeals and grievances processes should include:

- Requirements for plans to use medical necessity criteria that are objective, clinically valid, and compatible with generally accepted principles of care
- Conditions that plan denials, based on lack of medical necessity, explain in clear language the criteria used to make the determination
- Uniform exceptions and appeals processes and requirements for states to perform plan oversight
- Easy-to-access plan grievances processes and a system to track grievances and oversee plan responses to grievances filed
- Navigator programs that are available to guide patients through the complexities of plan appeals processes

Federal and State Oversight to Ensure Access

Second, the EHB regulation should include specific federal and state oversight requirements to ensure that qualified health plans meet all appropriate and necessary criteria. The ACA leaves substantial discretion to states to oversee qualified health plans operating on state Exchanges. Currently, states are engaged in widely different levels of Exchange implementation activity, with some state governors refusing all participation in Exchange development. To ensure adequate patient protection, the federal government may need to intervene or assist in the development of Exchange oversight activities in certain states.

HHS may consider as a model for appropriate oversight one of the two state Exchanges already in operation—the Massachusetts Health Connector. The Commonwealth Choice program offers a variety of plans with different benefit packages. Each year, the Health Connector reviews and approves each plan offered in Commonwealth Choice.

Federal and state oversight requirements should include:

- The development of baseline criteria for qualified health plans to ensure that minimum patient protections exist in all state Exchange plans, regardless of the state
- Federal fallback processes for states not performing adequate oversight of Exchange plans
- Requirements for qualified health plans utilizing a provider network to demonstrate an adequate number of in-network providers in various specialties corresponding to the EHB categories of health services

Conclusion

The NHC's unique perspective as a voice for the many people with chronic diseases and disabilities and their family caregivers has led to the NHC's interest in the successful establishment and implementation of the EHB package.

Based on its analysis, the NHC believes that a spectrum of patient protections are critical to the success of qualified health plans and Exchanges and to the health needs of the many people who will rely on EHB. Qualified health plans offering EHB will be a critical, if not sole, option for health insurance coverage for the millions of people who are expected to enroll. As HHS finalizes the establishment of the essential health benefits, the NHC strongly encourages the agency to include in its regulations the continuum of patient protections supported in this letter.

To reiterate, while the NHC's recommendations in this letter build the case for specific patient protections to be included in the EHB regulations that will safeguard people as they enroll in and navigate qualified health plans, they intentionally omit any reference to specific services or the categories of services included in essential health benefits. Rather, this letter articulates a regulatory approach to ensure patient protections for a robust and affordable health care benefit.

Appendix: Proposed Language for Regulations Related to Essential Health Benefits

The following regulatory language reflects the National Health Council's position on a subset of issues likely to be covered by the forthcoming regulations relating to the ACA's essential health benefits and Exchange requirements.

While the NHC's recommendations in this letter build the case for specific patient protections to be included in the EHB regulations that will safeguard people as they enroll in and navigate qualified health plans, they do not address specific services or the categories of services included in essential health benefits. Rather, this letter articulates a regulatory approach to ensure patient protections for a robust and affordable health care benefit.

Although the model regulations below follow the general organizational structure of NHC's policy recommendations, they are presented in a different sequence for the purpose of continuity.

Level 1

Balancing Cost and Quality

- 101. Barring Discrimination in Utilization Management
- 102. Ensuring Continuity of Care
- 103. Requiring Cost-Sharing Protections

Level 2

Establishing Patient and Consumer Supports

- 201. Patient Protections, General
- 202. Education and Care Coordination through Exchanges
- 203. Care Coordination and Management Activities

Level 3

Requiring Mechanisms to Ensure Access

- 301. Medical Necessity Decision Making and Appeals Processes
- 302. Ensuring Access to Essential Health Benefits through Exchanges

Appendix: Proposed Language for Regulations Related to Essential Health Benefits

Level 1: Balancing Cost and Quality

§ 101. Barring Discrimination in Utilization Management

(a) *Nondiscrimination in utilization management.* No health benefit plan shall engage in utilization management practices that discriminate against any person based on their race, religion, national origin, sex, sexual orientation, marital status, health status, personal appearance, political affiliation, source of income, age, or the presence of any sensory, mental, or physical disability.

(b) *Oversight mechanisms required.* States must establish oversight mechanisms to ensure that qualified health benefit plans meet all appropriate and necessary criteria relating to utilization review processes.

(1) State oversight required. States shall establish oversight mechanisms to review enrollee discrimination claims related to plan utilization management policies.

(2) Federal oversight required. HHS shall have final authority to approve state oversight programs to ensure appropriate measures are in place to guarantee that plans are meeting the requirements of this section.

§ 102. Ensuring Continuity of Care

(a) *Treatment protocols transferable.* A qualified health benefit plan must provide an appropriate transition process for enrollees who switch between plans or who switch between a plan and the Medicaid program. The transition process must preserve treatment protocols so that enrollees do not have to re-establish the necessity of treatment protocols already in place. In cases where the enrollee is switching between a qualified health benefit plan and the Medicaid program, the applicable state Exchange entity shall coordinate with the health benefit plan to ensure a seamless transition.

(b) *Eligible enrollees.* The transition process must be applicable to all of the following:

- (1) New enrollees following an open enrollment period;
- (2) Newly eligible enrollees from the Medicaid program or other coverage;
- (3) Enrollees who switch from a plan to the Medicaid program;
- (4) Individuals who switch from one plan to another after the start of the contract year; and
- (5) Current enrollees remaining in a plan who are affected by new restrictions on treatment protocols.

(c) *Transition process, minimum requirements.* At minimum, a transition process must ensure the following:

- (1) Enrollees have ready access to materials, in print and electronic form, that describe in plain language the plan transition process. These materials must include information about the timeline of the process, the appropriate plan and Exchange representatives to contact, and any additional information that would be beneficial to enrollees during the process;

(2) Involvement of case managers or care coordinators in relaying information on available services for adults with special health care needs, such as available funding for equipment; and

(3) Communication between plan physicians through the first 60 days of the transition process, so that the process is easier and all parties are informed.

(d) *Notice requirements.* An insurer shall provide in the policy, contract, and certificate written notice of the right to transfer treatment protocols.

(e) *Navigator education programs required.* States must establish education programs as part of the Navigator program to provide enrollees and prospective enrollees with information about switching between plans. Educational resources must include at a minimum the following:

(1) Print materials. Materials, made available both in electronic and print format, describing in plain language the plan transition process, the right to transfer treatment protocols, and the implications of changing plans on continuity of care. The applicable Exchange entity shall ensure that the information is presented in a culturally and linguistically appropriate manner and utilizes terminology understandable by the average plan enrollee.

(2) Live assistance. Dedicated staff members, available both by telephone and in-person, to answer enrollee questions and guide the enrollee through the plan transition process.

§ 103. Requiring Cost-Sharing Protections

(a) *In General.* A health benefit plan may impose varied levels of co-payments, deductibles, and co-insurance, provided that

(1) co-payments, deductibles, and co-insurance levels comply with the requirements of the Affordable Care Act (ACA); and

(2) the plan discloses to prospective enrollees in writing and in plain language the deductible, co-payment, and co-insurance amounts applicable to in-network and out-of-network covered services; and

(3) the plan discloses to enrollees in writing in plain language, the deductible, co-payment, and co-insurance amounts applicable to in-network and out-of-network covered services, and such notices are shared with enrollees whenever there is a change in services provided.

(b) *Specialty tiers prohibited.* In order to ensure that a health benefit plan does not discourage enrollment by specific patient populations reliant upon certain medications, no health benefit plan that provides coverage for prescription drugs and for which cost-sharing, deductibles, or co-insurance obligations are determined by category of prescription drugs shall impose cost-sharing, deductibles, or co-insurance obligations for any prescription drug that exceeds the dollar amount of cost-sharing, deductibles, or co-insurance obligations for non-preferred brand drugs or its equivalent (or brand drugs if there is no non-preferred brand drug category).

(c) *Cost-sharing for certain prescription drugs.* In order to ensure that a health benefit plan does not substantially discourage enrollment by specific patient populations reliant upon certain medications, health benefit plans that provide coverage for prescription drugs and for which cost-sharing, deductibles, or co-insurance obligations are determined by category of prescription drugs must comply with the following:

(1) Cost-sharing restrictions. Any cost to the enrollee associated with a high cost prescription drug shall not exceed the lesser of a \$250 co-payment or 25% co-insurance per drug per month in 2014 and

no enrollee's total cost-sharing for prescription drugs shall exceed \$500 per month. High cost prescription drugs are defined as any drug for which the negotiated price is \$600 per month or more, as defined in the Medicare Part D annual call letter. The co-payment amount shall be updated annually, using the annual percentage increase in the Consumer Price Index (CPI).

(2) Tiering Exceptions. If a health benefit plan utilizes a tiered cost-sharing structure to manage its drug benefits, the plan must establish and maintain reasonable and complete exceptions procedures that permit enrollees to obtain a non-preferred drug at the more favorable cost-sharing terms applicable to drugs in the preferred tier.

(d) *Uniform disclosure format*. Health benefit plans shall use uniform explanation of coverage forms developed by HHS in consultation with the National Association of Insurance Commissioners (NAIC), pursuant to §2715 of the Public Health Service Act (PHSA).

(e) *Failure to disclose cost-sharing*. A health benefit plan that willfully fails to provide the information required under this section shall be subject to a fine of not more than \$1,000 for each such failure. Such failure with respect to each enrollee shall constitute a separate offense for purposes of this subsection.

Level 2: Establishing Patient and Consumer Supports

§ 201. Patient Protections, General

(a) *Right to appeal adverse benefit determinations and file grievances*. Any inquiries, complaints, or grievances by an enrollee against a qualified health benefit plan or any appeal by an enrollee from an adverse benefit determination by a qualified health benefit plan shall be subject to the review and appeals procedures of the applicable state oversight entity.

(b) *Adverse benefit determination defined*. The term "adverse benefit determination" means any of the following: a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit, including any such denial, reduction, termination, or failure to provide or make payment that is based on a determination of a participant's or beneficiary's eligibility to participate in a plan, and including, with respect to group health plans, a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit resulting from the application of any utilization review, as well as a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.

(c) *Notice of material administrative changes required*. Health benefit plans must provide to enrollees notice of material administrative changes to plans at least 60 days in advance of such change.

(1) Content. This document must explain material administrative changes with rating impact, including covered benefit level changes, member cost-sharing changes, elimination of plans, implementation of new plan designs, provider network changes, new utilization or prior authorization programs, changes to eligibility requirements, changes to exclusions, or any other change in the plan offerings that impacts costs or coverage provided. The notice must also inform the enrollee of his or her right to opt out of the administrative change, as described in subparagraph (2) below.

(2) Special enrollment period triggered. If a health benefits plan makes administrative changes that would cause an enrollee to lose health benefit coverage, end the enrollee's relationship with a health care professional or provider, or otherwise cause undue hardship, the enrollee shall be entitled to participate in a special enrollment period to choose another qualified health plan.

(3) Length of special enrollment periods. A qualified individual or enrollee has 60 days from the date of a triggering event to select a qualified health plan.

(d) *Plan communications culturally and linguistically appropriate*. Health benefit plans shall provide relevant notices in a culturally and linguistically appropriate manner, in accordance with the requirements described in 45 CFR 147(e).

(e) *Oversight*. HHS will have final authority to review appeals and grievances related to adverse benefit determinations as defined in this subsection.

§ 202. Education and Coordination through Navigators

(a) *Education through Navigator program*. Navigator programs must include resources to educate individuals of their plan rights and responsibilities. Educational resources must include at a minimum:

(1) Print materials. Materials, made available both in electronic and print format, describing in plain language plan rights and responsibilities. The applicable Exchange entity shall ensure that the information is presented in a culturally and linguistically appropriate manner and utilizes terminology understandable by the average plan enrollee.

(2) Live assistance. Dedicated staff members, available both by telephone and in-person, to answer enrollee questions relating to enrollee plan rights and responsibilities.

(b) *Equal access to educational resources*. Educational resources must be made available to all enrollees, patients, and consumers, whether they have public or private insurance, and must take into consideration the individual's sensory, mental, or physical ability.

(c) *Marketing prohibited*. Educational materials and programs must be presented in an unbiased way that does not steer, or attempt to steer, the enrollee toward a specific plan or limited number of plans.

(d) *Navigator programs to coordinate with consumer assistance programs*. Navigator programs shall coordinate with other consumer assistance programs in the state to ensure that assistance is available to as wide a population as feasible. The applicable Exchange entity shall ensure that the assistance is available in a culturally and linguistically appropriate manner and utilizes terminology understandable by the average plan enrollee.

§ 203. Care Coordination and Management Activities

(a) *Care coordination included in essential health benefits package*. Care-coordination activities shall be included as an essential health benefit as required by 1302(b) of the Affordable Care Act.

(b) *Enforcement*. States must establish enforcement mechanisms to ensure that health benefit plans participating in the Exchange compensate providers for effective care coordination. Enforcement mechanisms shall include at minimum:

(1) Annual review. Annual review of health benefit plan provider compensation policies, including a review of financial incentives used to promote care-coordination or related strategies.

(2) Decertification. Health benefit plans failing to include financial incentives for care-coordination or related activities shall be decertified from qualified health plan status. In the event of a decertification, the Exchanges are responsible for notifying the QHP issuer, Exchange enrollees, HHS and the State Department of Insurance.

(c) *Effective care coordination defined.* Care-coordination activities shall be deemed “effective” if they result in a measurable improvement in outcomes for participating enrollees, compared to a similar risk-adjusted population within the state not participating in care coordination activities. Quality measures used for purposes of this section shall at a minimum include those approved by the Physician Consortium for Performance Improvement (PCPI) and endorsed by the National Quality Forum (NQF).

(d) *Encouraging pathways for innovative strategies.* State Exchange design and related policies must encourage and support the creation of innovative strategies that compensate providers for effective care coordination.

(e) *Care coordination information on Exchange websites.* Information about care-coordination policies of all participating health benefit plans shall be clearly posted on state Exchange websites and in all plan informational and marketing materials.

Level 3: Requiring Mechanisms to Ensure Access

§ 301. Medical Necessity Decision Making and Appeals Processes

(a) *Use of medical necessity criteria.* Health benefit plans may use a medical necessity determination process to make coverage decisions. Medical necessity decisions must be objective, clinically valid, and compatible with generally accepted principles of care.

(b) *Medical necessity.* A health intervention shall be covered if it is an otherwise covered category of service, not specifically excluded, recommended by the treating health care professional recognized under state or federal law, and determined by the health plan’s medical director to be medically necessary as defined in subparagraph (1) of this subsection. A health intervention may be medically indicated and not qualify as a covered benefit or meet the definition of medical necessity. A managed care plan may choose to cover health interventions that do not meet the definition of medical necessity.

(1) Required criteria. A health intervention is medically necessary if it is recommended by the treating physician or treating health care professional recognized under state or federal law, is approved by the health plan’s medical director or physician designee, and is

(A) For the purpose of treating a medical condition;

(B) The most appropriate delivery or level of service, considering potential benefits and harms to the patient; and

(C) Known to be effective in improving health outcomes; provided that:

(i) Effectiveness is determined first by scientific evidence;

(ii) If no scientific evidence exists, then by professional standards of care; and

(iii) If no professional standards of care exist or if they exist but are outdated or contradictory, then by expert opinion.

(2) Explanation of adverse determination required. Plan denials of benefits based on medical necessity shall explain in plain language the criteria used to make the determination. The explanation must include at minimum the following:

(A) The specific reason or reasons for the adverse determination;

(B) Reference to the specific plan provisions on which the benefit determination is based;

(C) Identification and description of the decision-making body responsible for making determinations;

(D) A statement that the enrollee is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the enrollee's claim for benefits;

(E) A statement describing appeal procedures offered by the plan and the enrollee's right to obtain the information about such procedures;

(F) Provide for a review that takes into account all comments, documents, records, and other information submitted by the enrollee relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination.

(3) Oversight. The applicable state oversight entity shall have the authority to review the medical necessity and clinical appropriateness of a covered benefit or service and shall ensure the right of a recipient to appeal an adverse benefit determination.

(c) *Exceptions process*. Each health benefit plan must develop its own exceptions process under which a plan enrollee may ask the plan to cover a health service or drug that does not meet the medical necessity criteria in subsection (b). At a minimum, health benefit plan exceptions processes must meet the following requirements:

(1) General requirements. A plan enrollee, the enrollee's appointed representative, or the enrollee's health care professional recognized under state or federal law may request an exception based upon an individual patients' predicaments, rights, needs and preferences in making clinical decisions about their care. An appointed representative includes someone who is appointed by an enrollee to act on behalf of the enrollee in the claims and appeals process or someone who is authorized under state or other law to act on behalf of the enrollee.

(2) Health professional participation. Even if the exception is requested by an enrollee or an appointed representative, the enrollee's health care professional recognized under state or federal law must participate in the process by providing the medical information required by the plan.

(3) No specific form requirements. Health benefit plans are required to accept any request or supporting statement that is made in writing, and are prohibited from requiring a health care professional to make a written request or submit a supporting statement on a specific form.

(4) Review of evidence in support of an exception. Each health benefit plan shall develop its own procedures and evidentiary requirements. A plan must inform the enrollee and the health care professional of its decision on an exceptions request within 72 hours after receipt of the health care professional's supporting statement, or as expeditiously as the enrollee's health condition requires. If the enrollee requests expedited consideration, the decision must be made within 24 hours of receipt of the health care professional's statement or as expeditiously as the enrollee's health condition requires.

(5) Notification of exceptions decision. If the plan fails to make a determination and notify the enrollee within the required time frame specified in paragraph (e)(4) of this subsection, the exception request is deemed to be accepted. If the request is denied, the enrollee is entitled to an appeals process as described in paragraph (d) of this subsection.

(d) *Appeals process for adverse coverage determination*. Enrollees are entitled to a reasonable opportunity for a full and fair review of an adverse coverage determination.

(1) Notice of right to appeals process. The enrollee shall receive a notice in writing of a coverage decision. The notice must include a notice of the right to a hearing with the appropriate hearings office, of the method by which a hearing may be requested, and of the right to use an appeals representative.

(2) Full and fair review. The health benefit plan will not be deemed to provide an enrollee with a reasonable opportunity for a full and fair review of a claim and adverse benefit determination unless the claims procedures

(A) Provide enrollees at least 60 days following receipt of a notification of an adverse benefit determination within which to appeal the determination;

(B) Provide enrollees the opportunity to submit written comments, documents, records, and other information relating to the claim for benefits;

(C) Provide that an enrollee shall be provided, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the enrollee's claim for benefits.

(3) Timing. When a patient or a provider first appeals the decision of an insurer to deny treatment or payment for services as not medically necessary or experimental, or to deny a request for exception

(A) the insurer shall acknowledge receipt of the notice of appeal not later than the seventh day after receiving the notice; and

(B) an appropriate medical consultant or peer review committee shall review the appeal and decide the issue not later than the 30th day after the insurer receives notice of the appeal.

(4) Review. When the treating health care provider and the health plan's medical director or physician designee do not agree on whether a health intervention is medically necessary, a reviewing body, whether internal to the plan or external, shall give consideration to, but shall not be bound by, the recommendations of the treating health care provider and the health plan's medical director or physician designee.

(5) Appeals and grievances posted publicly. Health benefit plans shall post all appeals and grievances filed on their website and with the applicable Navigator program, in a manner compliant with the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (P.L.104 -191) (HIPAA).

(6) Oversight. Once the appeals process provided by the plan is exhausted, enrollees are entitled to a fair hearing with the applicable state oversight entity. The oversight entity has the final authority to reverse a plan determination if it finds that the plan did not provide the enrollee with an adequate appeals process, or if it finds evidence of discriminatory practices. The applicable oversight entity must also ensure that the appeals and grievances process provides adequate whistleblower protections, as described in paragraph (e) of this subsection.

(e) Protection for Reporting.

(1) Prohibition of retaliation or discrimination. A health benefit plan shall not discriminate or retaliate in any manner against any enrollee, employee, or contract employee of the plan, or any other individual, on the basis that such individual, in good faith, individually or in conjunction with another person or persons, has presented a grievance or complaint, or has initiated or cooperated in any investigation or proceeding of any governmental entity, regulatory agency, or private accreditation

body, made a civil claim or demand, or filed an action relating to the care, services, or conditions of the health benefit plan or of any affiliated or related entities.

(2) Good faith defined. For purposes of this subsection, an individual shall be deemed to be acting in good faith if the individual reasonably believes

(A) the information reported or disclosed is true; and

(B) a violation of this title has occurred or may occur.

(f) *Navigator program to support appeals process.* Navigator programs shall include resources to guide and assist patients through the health benefit plan appeals processes. Guidance resources must include at a minimum:

(1) Print materials. Materials, made available both in electronic and print format, describing in plain language the appeals process. The applicable Exchange entity shall ensure that the information is presented in a culturally and linguistically appropriate manner and utilizes terminology understandable by the average plan enrollee.

(2) Live assistance. Dedicated staff members, available both by telephone and in-person, to answer enrollee questions relating to the appeals process.

§ 302. Ensuring Access to Essential Health Benefits through Exchanges

(a) *Quality assurance.* Each State Exchange shall have systems in place to monitor and seek to improve the quality of care provided to enrollees, and shall continuously improve on methods to measure, monitor, and disclose quality performance.

(b) *Patient protection.* State Exchanges shall adopt and implement policies to facilitate each enrollee's ability to receive timely and appropriate health care by qualified health benefit plans and health care providers, while protecting enrollees' personal health information in accordance with applicable state and federal law.

(c) *Habilitation services required.* Health insurance plans must provide coverage for habilitation services for any member with one or more cognitive, emotional, or physical conditions or disabilities. For purposes of this section, "habilitation services" shall be defined as the assisting of an individual with achieving skills when impairments have caused delaying or blocking of initial acquisition of the skills. Habilitation services may include cognitive, social, fine motor, gross motor, or other skills that contribute to mobility, communication, and performance of activities of daily living and enhance quality of life.

(d) *Non-discrimination.* The Exchange and participating health benefit plans shall not use any policy or practice that has the effect of excluding an eligible individual from coverage or discriminating against an eligible individual or enrollee because of race, religion, national origin, sex, sexual orientation, marital status, health status, personal appearance, political affiliation, source of income, age, or the presence of any sensory, mental, or physical disability.

(e) *Redress for discrimination claims.* Enrollees are entitled to a fair hearing for real or perceived discrimination based on reasons described in paragraph (c) of this section. States shall establish with the Exchange entity an administrative judicial process to hear enrollee claims based on discrimination. Once administrative remedies are exhausted, enrollees may file their claim in a federal court. If the state fails to establish an administrative judicial process for discrimination claims, the enrollee will be deemed to have exhausted administrative remedies.

(f) *Network requirements.*

(1) Network design. Health benefit plans utilizing a provider network shall be required to demonstrate an adequate number of in-network providers in various specialties corresponding to the ten categories of essential health benefits services. Network designs must encourage a choice of provider networks, promote cost-effective delivery of health care, and assure geographic access.

(2) Specialty provider. Health benefit plans must ensure that enrollees have access to specialty providers that meet the needs of patients. Specialty provider availability must take into account the geographic prevalence of the enrollees' specific conditions.

(3) Geographic access. Health benefit plans must demonstrate that their networks do not unduly burden beneficiaries in terms of travel distance and time to network providers. Health benefit plans must demonstrate that 90% of their provider network meets the time and distance requirements (90% of beneficiaries must have access to at least one provider, for a given specialty, within the time and distance requirements). Time and distance requirements for urban, suburban, rural, and frontier localities shall be established by HHS.

(4) Written information required. If a health plan has a defined network of participating providers, the plan must provide enrollees with written general information, in a culturally and linguistically appropriate manner that includes a list of all primary care providers and direct access providers, and may also include a list of all specialty care providers.

For the purposes of this paragraph, a primary care provider or direct access provider is a participating provider under the terms of the plan who an enrollee may designate as the primary care provider for the enrollee or from whom an enrollee may obtain services without referral. The list of providers must include for each provider the provider's name, professional designation, category of practice and the city in which the practice of the provider is located. If the information does not list participating specialty care providers, the information must state that fact and must disclose the manner in which an enrollee may obtain information about participating specialty care providers.