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October 31, 2011

The Honorable Kathleen Sebelius
Secretary of Health & Human Services
Hubert H. Humphrey Bldg., Room 120F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Establishment of Exchanges and Qualified Health Plans CMS-9989-P

Dear Secretary Sebelius:

National Patient Advocate Foundation (NPAF) is the voice for millions of patients who have sought care after a diagnosis of a chronic, debilitating or life-threatening illness. Its advocacy activities are informed and influenced by the experience of patients who receive direct, sustained services from its companion organization, Patient Advocate Foundation (PAF), a business that employs 212 people in 9 states. Founded in 1996, PAF is a national non-profit, 501(c)(3) direct patient services organization with a mission "to safeguard patients through effective mediation assuring access to care, maintenance of employment and preservation of their financial stability." PAF provides professional case management assistance to patients with chronic, debilitating or life-threatening conditions.

PAF serves as an active liaison between patients and their insurer, employer and/or creditors to resolve insurance, job retention, and/or debt crisis matters relative to their diagnosis through professional case managers and a national network of health care attorneys. PAF case managers work with patients and their providers to identify local, state, and federal programs that provide assistance for their individual needs, ensure appropriate reimbursement for healthcare services by their insurers and educate them on their employment rights during an illness. In 2010, PAF resolved 82,963 patient cases and received more than four million additional inquiries from patients nationally.

NPAF appreciates the opportunity to provide comments on the establishment of Exchanges and qualified health plans as provided in the Patient Protection and Affordable Care Act (PPACA).¹ NPAF understands Health and Human Services' (HHS) desires to design exchanges in a manner that improves accessibility, affordability and quality of care for patients. The proposed regulation² outlines standards for States relative to the establishment of Exchanges and outlines standards required of Exchanges related to minimum Exchange functions. It also outlines the proposed standards for health insurance issuers with respect to participation in an Exchange, including the minimum certification requirements for qualified health plans (QHPs).

The comments found in the balance of this letter are informed by the collective experiences of patients who have contacted PAF for assistance in accessing quality care.

¹ Pub.L. 111-148.

² 76 Fed. Reg. 41866 (July 15, 2011)

Those experiences have been quantified in the PAF's Patient Data Analysis Report (PDAR) which illustrates the data collected across 260 variables by PAF senior case managers. As noted above, PAF resolved 82,963 patient cases and received more than four million additional inquiries from patients nationally in 2010. Thus, while HHS staff will certainly review an unprecedented number of perspectives regarding the proposed regulation, NPAF's perspective is an invaluable one as it reflects the quantification of over a decade and a half of collective patient experience in health system navigation.

NPAF appreciates the HHS perspective that it must identify how best to balance the need for State flexibility against the need for consistency in drafting general standards related to the establishment of an Exchange by a state. NPAF recognizes that HHS must also consider current and future state Constitutional Tenth Amendment challenges to the PPACA when drafting Exchange regulations. The Tenth Amendment states, "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." This language and the issues of federalism it engenders have been the basis of challenges to the Patient Protection and Affordable Care Act (PPACA). While the debate regarding whether the Tenth Amendment reserves a zone of authority exclusively to the states thereby limiting Congress's power will certainly continue, NPAF encourages HHS to balance the importance of state sovereignty with the need to assure patient-specific benefits of the PPACA are not eroded. NPAF notes the regulations do not require states to negotiate with plans on price or benefit offerings. This omission represents a missed patient-specific opportunity to assure qualified health plan products that are attractively priced yet benefit-rich.

General Standards Related to the Establishment of an Exchange by a State

a. Establishment of a State Exchange

NPAF applauds HHS' observation that States should consider the relative merits of operating an Exchange through a non-profit entity. Certainly non-profit entities may be able to operate without some of the restrictions that can limit the flexibility of governmental agencies.

NPAF State Exchange Establishment Recommendations While NPAF also agrees that nonprofit agencies may face limitations performing functions that are typically governmental in nature, future federal regulations can be drafted in a manner that removes some of those stated limitations to capitalize on the benefits nonprofits possess. For example, nonprofits clearly have gained the trust of communities. As an article in *Health Affairs* noted, "The potential responsiveness of the nonprofit sector to community preferences seems the antithesis of "micromanagement" by government. . . ." ³ This community perception of government versus nonprofits is an important one. Clearly community trust in the concept of purchasing health insurance through an Exchange will be a necessary building block in gaining individual consumer trust.

HHS should also note that the issue should not be framed in the context of whether nonprofits face limitations performing functions that are typically governmental in nature but rather whether nonprofits or government are more likely to engender the trust of the healthcare consumer. Consumer trust will ultimately decide appropriate uptake of the qualified health plans sold by the Exchanges and directly impact PPACA's language that Exchanges are to "facilitate the purchase of qualified health plans."

b. Approval of a State Exchange

NPAF concurs with HHS's approach to establish a review process for the Exchange Plan that is similar to Medicaid and the Children's Health Insurance Plan for which there are 90 days to review

³ Mark Schlesinger and Bradford H. Gray *Health Affairs*, 25, no.4 (2006):W287-W303 How Nonprofits Matter In American Medicine, And What To Do About It; (published online June 20, 2006;10.1377/hlthaff.25.w287)

the plan for either approval or denial, or to request comment.⁴ NPAF also concurs with the approach identified by HHS that a state must notify HHS before significant changes are made to the Exchange Plan and that an Exchange must receive written approval of significant changes from HHS before they may be effective, a process which mirrors the current State Plan Amendment (SPA) process. NPAF recognizes this approach as a laudable first step. If the PPACA is to be patient-centric, then the patient voice must be heard and considered in the deliberative process. NPAF encourages HHS to amend the current SPA process by stipulating a requirement whereby the public has the opportunity to comment on any amendments and HHS has the responsibility to share a summary of those comments and how they were considered in the resultant Exchange plan amendment. The transparency between the states and HHS must be greater as Exchange operations will affect a far greater number of people.

c. Entities Eligible to Carry Out Exchange Functions

NPAF is encouraged by HHS's statement requesting comment on the extent to which HHS should place conflict of interest requirements on Exchange contracting arrangements with outside entities. NPAF understands the strength that public-private partnerships can bring to the Exchange implementation effort. States will not be able to conduct all of the Exchange responsibilities without tapping into the financial, human resource and intellectual capital of the private sector. Such partnerships allow governments to leverage limited resources. However, these partnerships should be constructed in a manner that protects the health consumer. Such protection is only possible if there is full transparency of the entire contracting arrangement. While HHS is interested in placing conflict of interest requirements on contracted entities, without first requiring full transparency, the conflict of interest might not ever become apparent. Thus, HHS should first require transparency in all contracting relationships, including all subcontracts. The conflict of interest language in any such transaction must be far-reaching and include potential conflicts such as restrictions precluding those serving on the board from working for an insurer directly after leaving the board. To assure the conflict of interest requirements are adequate, NPAF recommends HHS review the Food and Drug Administration's conflict of interest rules outlined in its "Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees"⁵

NPAF Exchange Entity Eligibility Recommendation If the Exchange is an independent State agency or not-for-profit entity established by the State and not an existing State agency, the proposed rule requires the Exchange board to hold regular public meetings for which the public is provided advance notice to allow them opportunities to observe and comment on Exchange policies and procedures. In order for public participation to be meaningful, the public must have opportunity to observe and comment on *draft* Exchange policies and procedures. This approach favors the public as well as protects the Exchange from implementing unworkable policies. The Exchange should also be required to identify how the public comments were considered by tracking them and sharing how the comments were considered by the Exchange with the public.

The governance of an Exchange is of paramount importance. The proposed regulation language regarding Exchange governance should be more prescriptive in nature. For example, to assure the consumer perspective is considered, the regulations should stipulate that a consumer representative (both employer and employee) should hold a voting seat on the board. Also, the financial interest disclosure should include the spouses and families of the governing board. The timing for financial and other disclosure documents should be identified. NPAF recommends quarterly filings of the disclosure documents.

d. Stakeholder Consultation

⁴ 42 U.S.C. § 1396-1

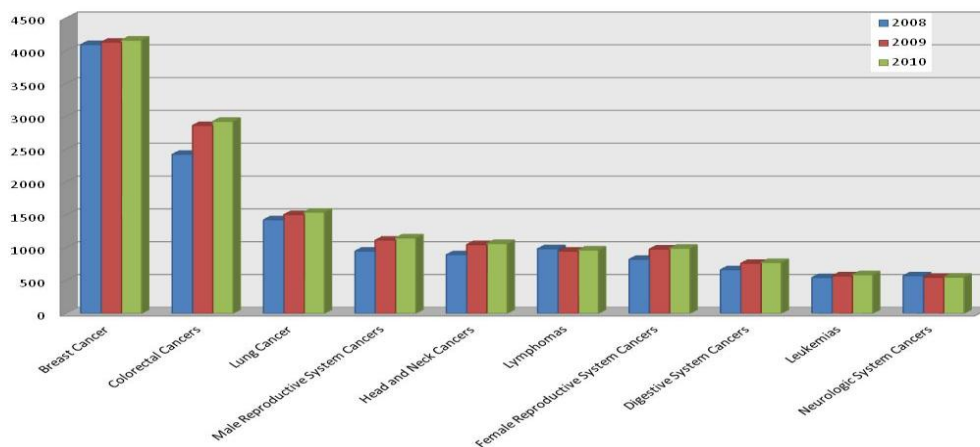
⁵ Available at <http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0101.gdl10001.pdf>

Section 1311(d)(6) of the Affordable Care Act requires Exchanges to consult with certain stakeholders throughout ongoing operations. The statute identifies some of the groups that are to be consulted, including entities with experience in facilitating enrollment in health coverage. The proposed regulation identifies additional groups, including Federally recognized tribes, public health experts, health care providers, large employers, health insurance issuers and agents and brokers.

NPAF Stakeholder Recommendations While the aforementioned groups are important, the omission of patient advocate groups as a clearly identified and therefore crucial stakeholder must be remedied. Patient advocate groups have the unique advantage of serving as the patient voice when the patient is unable. Challenges with Exchanges will become apparent when the healthcare consumer becomes a patient. The Exchange fails of its essential purpose if it merely satisfies the needs of healthcare consumers to purchase qualified health plans yet lacks the ability to assure consumers get the care they need from the plans when they become patients.

The need for patient advocates is also important because those that have been in existence for at least a decade have longitudinal data that can serve as Exchange sentinel data. Just as a sentinel health event monitors the rate of occurrence of specific conditions to assess the stability or change in health levels of a population, patient advocate sentinel data amplifies the challenges faced by those who are not merely attempting to get enrolled in health insurance, but who are actually in need of the services for which they have been paying premiums or on whose behalf premiums in the form of taxpayer dollars have been paid. For example, the chart below demonstrates the growing challenge patients diagnosed with colorectal cancer and breast cancer have with accessing care for services and can be compared to access challenges of those with other cancer diagnoses. Data like these can inform Exchange personnel of where best to focus their resources to address patient needs.

Exhibit 5: Top 10 Cancer Diagnosis Groups of PAF Patients (2008 - 2010)



General Functions of an Exchange

a. Required Consumer Assistance Tools and Programs of an Exchange

The PPACA⁶ requires Exchanges to operate a call center to respond to requests for assistance by consumers that is accessible via a toll-free telephone number. NPAF urges HHS to consider the evolution of the telephone and call centers. As the *Washington Post* reported on July 11, a third of all American adults own smart phones and for many minority and low income users, mobile devices have replaced computers for Internet access.⁷ A recent Pew Internet & American Life Project

⁶ Section 1311(d)(4)(B)

⁷Cecelia Kang, “As Smartphones Proliferate, Some Users are Cutting the Computer Cord” *Washington Post*, July 11, 2011

survey⁸ reveals consumers are adopting smart phones — faster than almost any other high-tech product in history. NPAF urges HHS to encourage state Exchanges to utilize this technology that has the potential to narrow the digital divide by designing application software or apps to capture this population. The use of social media should also be fully explored as its popularity increases.

NPAF Exchange Call Center Communication Recommendations The proposed rule seeks comments on ways to streamline and prevent duplication of effort by the Exchange call center and the Qualified Health Plan (QHP) issuers' customer call centers but ensure that consumers have a variety of ways to learn about their coverage options and receive assistance on other health insurance issues. NPAF advises HHS to adopt a “no wrong door” approach to this issue. A “no wrong door” approach allows for consumers to successfully purchase or enroll in health insurance products regardless of their location when they make such a request. As states have increased Medicaid enrollment by permitting multiple entities the ability to share information across automated information platforms, HHS might likewise consider this approach to serve both stated goals.

The call centers should adopt Medicare Part D call center specification.⁹ NPAF's companion organization PAF worked closely with Centers for Medicare and Medicaid leadership to improve the Medicare Part D enrollment process. That process has evolved into one that is far superior to the one designed at its inception. Examples of the specificity of the requirements include hours of operation which is 7 days a week, from 8am to 8pm according to the time zone for the regions in which it operates. It also dictates that 80 percent of the calls must be answered within 30 seconds and that the abandonment rate of all incoming calls are not to exceed 5 percent. Issuers that have qualified health plan products sold through the Exchange should likewise have to meet these Medicare Part D standards.

The proposed rule also provides information regarding the operation of a website in accordance with PPACA.¹⁰ A number of states have website materials that describe Exchanges as a Travelocity, Expedia, Priceline product for purchasing health insurance. NPAF encourages HHS to consider the ease in which the consumer can purchase travel products on these sites and leverage that success when defining State Exchange requirements. However, HHS should also note that these sites are designed to increase the profit margins of their participants. State Exchange websites should be designed in a manner that not only promotes full disclosure, but prompts the consumer to consider consequences he may or not have contemplated. For example, if he or she purchases or inquires about a bronze level product, screens should pop up not only highlighting the benefits of health insurance coverage, but educating the consumer on the limitations of bronze level products. Such a process promotes true informed consent and minimizes post purchase dissonance.

Information provided to consumers on the scope of QHPS should not be limited to price information but should include quality measures. Quality measures should not be limited to Healthcare Effectiveness Data and Information Set (HEDIS) and Consumer Assessment of Healthcare Providers and Systems (CAHPS) scores. The quality measures need to be understandable to consumers and need to include measures that consumers value. For example, they should include patient-centric measures such as measures of pre- and post-treatment functional status, appropriateness of care and like measures.

To assure all eligible consumers, including the disabled are able to access Exchange, NPAF encourages HHS to require automated systems to include usability features or functions that accommodate the needs of persons with disabilities, including those who use assistive technology. While NPAF recognizes State enrollment and eligibility systems are subject to the program

⁸ Aaron Smith, “Americans and Their Cell Phones” Pew Internet & American Life Project (published online August 15, 2001) <http://pewinternet.org/~media/Files/Reports/2011/Cell%20Phones%202011.pdf>

⁹ See <https://www.cms.gov/PrescriptionDrugCovContra/downloads/PartDCallCtrRequirements.pdf>

¹⁰ Section 1311(d)(4)(C)

accessibility provisions of Section 504 of the Rehabilitation Act, which include an obligation to provide individuals with disabilities an equal and effective opportunity to benefit from or participate in a program, it encourages HHS to communicate with patient advocate groups on a regular basis to assure continued compliance with the Act by Exchanges.

Eligible consumers include those with limited English proficiency (LEP). To assure the LEP population benefits from culturally and linguistically appropriate information, Exchanges must comply with section 1557 of the PPACA and exchanges receiving federal financial assistance must comply with both Title VI of the Civil Rights Act as well as section 1557 of the Act.

a. Navigator Program Standards

While all components of an Exchange must work well both individually and collectively, the keystone to successful Exchange operations is the ease of the enrollment process. Its quantitative outcome will become the metric by which Exchange success will be judged. Navigator duties are important ones and are identified in section 3510 of the ACA. Essentially, the statute requires navigators to:

- (A) conduct public education activities to raise awareness of the availability of qualified health plans;
- (B) distribute fair and impartial information concerning enrollment in qualified health plans, and the availability of premium tax credits under section 36B of the Internal Revenue Code of 1986 and cost-sharing reductions under section 1402;
- (C) facilitate enrollment in qualified health plans;
- (D) provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the Public Health Service Act, or any other appropriate State agency or agencies, for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage; and
- (E) provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange or Exchanges.

While the term “facilitate enrollment” is not explained in detail, it likely refers to the essential role navigators will play in educating consumers about exchanges. Because the navigator role as an educator serves as a catalyst that ignites the process of exchange offering and health consumer insurance product “take up,” those who serve as navigators must be able to perform the aforementioned roles well. In recognition of the important role navigators will play and to assure the navigator role does not become compromised, the PPACA directed HHS to establish standards that include provisions ensuring:

- “ that any private or public entity that is selected as a navigator is qualified, and licensed if *appropriate*, to engage in the navigator activities described in this subsection and to avoid conflicts of interest. Under such standards, a navigator shall not—
- (i) be a health insurance issuer; or
- (ii) receive any consideration directly or indirectly from any health insurance issuer in connection with the enrollment of any qualified individuals or employees of a qualified employer in a qualified health plan.”¹¹

These standards protect against conflict of interest and assure flexibility in the types of entities that can serve in the capacity of a navigator. The proposed rule prohibits navigators from having a conflict of interest, stated as receiving remuneration, directly or indirectly, from a health insurance issuer in connection with the enrollment of qualified individuals or businesses in a QHP offered through the Exchange during the term of their grant. This rule preserves navigator integrity. However, allowing navigators to receive compensation from health insurance issuers in connection with the enrollment of individuals, small employers or large employers in non-QHP erodes that

¹¹ Ibid

integrity. The result of the proposed rule may encourage adverse selection by essentially creating a system which induces referrals outside of the Exchange.

NPAF Navigator Recommendations The statute also identifies a number of entities that can serve as navigators, including but not limited to, trade, industry, and professional associations, commercial fishing industry organizations, ranching and farming organizations, community and consumer-focused nonprofit groups, chambers of commerce and unions. While the breadth of entities afforded the ability to serve as navigators is commendable, NPAF recommends that the certification referenced in 45 CFR 155.210(b)(iii) assures their ability to competently perform navigator duties. The navigator certification process should be tiered so that consumers will be able to differentiate the navigators that are from patient advocacy groups with considerable experience in insurance enrollment from those navigators enrolling patients in insurance products for the first time.

NPAF strongly supports the suggested alternative that HHS require that at least one of the two types of entities serving as Navigators include a community and consumer-focused non-profit organization. Absent such a requirement, the Exchange will not be consumer-centric. These groups are the only ones with a strong track record in securing consumer/patient trust. Finally, existing entities which rate the abilities of other organizations such as guidance of Guidestar and Charity Navigator in the case of nonprofits should be consulted to perform certification activities. At a minimum, the entities which will perform this role should ensure the organization requesting navigator status has a comprehensive understanding of the rules guiding Exchanges and adheres to best practices in their respective fields.

The proposed regulation should also encourage Exchanges to design web-based systems so that calls to Navigators can be documented with reference numbers as is done with Medicare Part D. The password-protected ability for both Navigators and consumers to later retrieve information can serve to validate the accuracy of information provided. This may prove to be essential to consumers who may have made an insurance enrollment decision based on incorrect information who may later want to avail themselves of the exceptional circumstance enrollment period.

Exchange consumers should be able to make informed decisions. Decisions can only be informed ones if there is full disclosure at every step of the enrollment process. Navigators should have to disclose any direct or *potential* conflict of interest. The disclosure information style should be consistent with all materials provided to consumers. The materials should be consistent with the standards related to the readability of Medicaid notices and program materials. The guide entitled, "Reading and Designing Print Materials for Beneficiaries: A Guide for State Medicaid Agencies"¹² is useful, but should be updated before the Exchanges are implemented.

Exchange Functions in the Individual Market

a. Enrollment of Qualified Individuals into Qualified Health Plans (QHPs)

NPAF is pleased that the proposed rule requires Exchanges to draft applications, forms, and notices in plain language. The vast array of templates and standard forms that will be necessary for the successful operation of an Exchange will be considerable. As noted above, Exchange operations can benefit greatly from the improvements patient advocacy groups suggested for the Medicare Part D program. Many of them have been implemented and contribute to its success today. NPAF recommends HHS also adopt the color-coding process the Social Security Administration utilizes to reduce errors in submitting the correct form. This can be particularly helpful to distinguish the different types of qualifying events for enrollment. In addition to color-coding the forms, application forms should include an option for all questions allowing the consumer to state an option does not apply to him or to her. This option will prevent automated systems from rejecting submissions that may appear to be incomplete. The proposed rule also queries whether applicants should be allowed to refuse to answer questions that are not pertinent to the eligibility and

¹² U.S. Department of Health and Human Services, Health Care Financing Administration, Center for Medicaid and State Operations, *Reading and Designing Print Materials for Beneficiaries: A Guide for State Medicaid Agencies*, (Oct. 1999).

enrollment process. Once again, questions should include an option that allows a consumer to choose an option that states, "I do not care to respond to that question" in such instances.

NPAF Exchange Enrollment Recommendations Exchanges are most likely to overcome general challenges of adverse selection if the greatest possible number of people participate in its offerings. NPAF encourages HHS to provide guidance on enrollment period issues by employing a process that allows for the most generous reading of time intervals, particularly in the first year of Exchange operations. The 60 day special enrollment period should begin on the first date in which a consumer experiences a change in eligibility. Termination of coverage, whenever possible, should occur at the end of the month in which termination is requested. This approach would eliminate insurance coverage policy gaps.

Those enrolled in exchanges should receive the benefits of effective care coordination and management. This approach supports not only the reduction of total health care costs but improves patient outcomes. If patients do not receive these benefits the Exchanges will merely further the health care system's challenges with delivering fragmented care which contribute to cost inefficiency and poor outcomes. NPAF encourages HHS to adopt the National Quality Forum's (NQF) definition of care coordination. It is defined by NQF 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."¹³ Patient navigators are uniquely positioned to assure the care received by patients is indeed coordinated.

Efforts to assure adequate care coordination will prove useless if the regulations do not provide understandable and irrefutable language regarding medical necessity determinations. The process for enrollees to file appeals of adverse plan coverage determinations should be provided to them in multiple formats as well as periodically. The process should include ample participation by the two most important parties to such an appeal- the patient and his or her provider. Medical necessity criteria should be objective, clinically based and comport with generally accepted principles of care. The system used to track grievances should be made available to government entities and data that are not individually identifiable should be shared with patient advocacy groups. Finally, government agencies need to promote transparency by making public repeated plan failures to correct identified errors.

Again, NPAF appreciates the opportunity to provide comments on the establishment of Exchanges and qualified health plans as provided in the Patient Protection and Affordable Care Act. Please feel free to contact us should you need any additional information regarding how the Exchanges can be established in a manner most favorable to the health consumer.

Sincerely,



Nancy Davenport-Ennis
Chief Executive Officer



Rene Cabral-Daniels
Executive Vice President of Regulatory Affairs

¹³ http://www.qualityforum.org/projects/care_coordination.aspx