

October 31, 2011

The Honorable Kathleen Sebelius, Secretary
United States Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Subject: *Notice of Proposed Rulemaking: Patient Protection and Affordable Care Act: Establishment of Exchanges and Qualified Health Plans; 45 CFR Parts 155 and 156; CMS 9989-P*

Dear Secretary Sebelius:

We appreciate the opportunity to submit our comments and observations regarding the above-referenced proposed rule that strives to establish federal requirements that States must meet if they establish and operate an Exchange. The proposal also establishes standards related to selection and oversight of qualified health plans (QHPs) and the minimum requirements that health insurance issuers selling QHPs must meet in order to have their products certified for sale in an Exchange. The National Community Pharmacists Association (NCPA) represents America's independent community pharmacists, including the owners of more than 23,000 community pharmacies, pharmacy franchises and chains. We employ over 300,000 full-time employees and dispense nearly half of the nation's retail prescription medicines.

Specifically, NCPA would like to offer specific suggestions in the areas of proposed changes to a state's exchange plan; network adequacy standards for pharmacy services; essential community providers; and the required prescription drug reporting requirements.

Section 155.105(e) Significant Changes to the Plan

HHS seeks comment on whether the State Plan Amendment (SPA) process currently in place for Medicaid and CHIP should be used as a model for requesting and approval of changes to state exchange planning documents. While the SPA processes do allow for dialogue and technical assistance between CMS and the state as changes are being considered, the current SPA process is relatively opaque in terms of the amount of information available to impacted providers and beneficiaries.

CMS currently provides a limited amount of information about state plan amendments after they have progressed through the requisite procedural process; however, there is very little information available either from the individual state or CMS during the time that the SPA is being considered by CMS. In order to provide interested stakeholders with adequate information about what changes are being sought by the state and in order to determine the timeframe in which stakeholders may write to HHS/CMS about the pending amendment, information on the CMS website as to the date any changes were initially submitted or subsequently amended as well as the full text of the proposed amendment itself would be extraordinarily helpful. NCPA provided similar suggestions to CMS about the SPA process itself in July 2011 in response to the CMS proposed rule dealing with methods for assuring access to covered Medicaid services (CMS 2328-P).

Section 155.1050 Network Adequacy

Under this section, Exchanges must ensure that enrollees of QHPs “have a sufficient choice of providers.” HHS further provides in commentary that this provision was drafted very broadly so that network adequacy standards could be customized to be reflective of States’ particular “geography, demographics, local patterns of care, and market conditions.” While we appreciate the intent of HHS to afford states latitude in determining these standards, NCPA feels strongly that there need to be standardized access requirements for the provision of pharmacy services.

Appropriate access to pharmacy services is critical and may actually reduce utilization of more costly medical interventions. Community pharmacists provide expert medication counseling and other cost-saving services that help mitigate the \$290 billion annual cost of treating patients that do not adhere to their medication regimen. Pharmacists are also increasingly gaining recognition for the integral role they play in encouraging preventative care and promoting wellness, given their subject matter expertise and frequent contact with members of the communities in which they serve.

In Terms of Pharmacy Network Adequacy, Access to Mail Order Pharmacy Does not Equate with Access to Face-to Face Interaction With a Pharmacist

NCPA is concerned that some plan issuers may try to assert that mail order pharmacy is a cost-saving technique that can provide adequate access to pharmacy services. While NCPA does not oppose the offering of mail order pharmacy as one option that may be available to consumers, there are a number of critical factors that distinguish access to retail pharmacy from access to mail order pharmacy.

Community pharmacies represent the most accessible point in patient-centered healthcare where typically consumers do not need an appointment to talk with a pharmacist about prescription medication, over-the-counter products or any other health-related concern. This access and related counseling typically results in more effective medication use and optimized health care outcomes which may ultimately save money on averted downstream medical care. The 2011 CVS Caremark Trend report states that face-to-face counseling by local pharmacists is two to three times more effective at ensuring that patients adhere to their medication regime than any other type of intervention.

There have been no peer-reviewed studies that indicate that prescriptions purchased through mail order pharmacies are less expensive than those purchased at retail pharmacies and, when given a choice, most patients (83%) prefer to fill their prescription at a community pharmacy rather than a mail order pharmacy. Finally, mail order pharmacy may not be suitable for certain patient populations like the elderly or those with multiple chronic conditions, that typically benefit the most from personalized attention from their pharmacist.

To Assess the Adequacy of Access of Pharmacy Services, Exchanges Should Use the TRICARE Retail Pharmacy Access Requirements

Under the Department of Defense TRICARE program, prescription drug benefit plans are required to secure the participation of a sufficient number of pharmacies (not including mail service) in their pharmacy networks to ensure convenient beneficiary access. These standards require a certain percentage of beneficiaries to live within a certain number of miles of a retail pharmacy based on whether they reside in an urban, suburban or rural area. In urban areas, at least 90% of beneficiaries on average must live within two miles of a participating retail pharmacy; in suburban areas, at least 90% of beneficiaries on average must live within five miles of a participating retail pharmacy; and in rural areas, at least 70% of beneficiaries on average must live within fifteen miles of a participating retail pharmacy.

In addition, under current Medicare Part D standards, pharmacy networks must be at least as inclusive as those recognized under the TRICARE program. Part D and the TRICARE program recognize the fact that adequate access to retail pharmacy services are essential and must be evaluated based on the beneficiaries location in urban, suburban or rural areas. Ideally, Exchanges should allow all pharmacies that wish to participate be included in the network and consider the TRICARE/Part D retail pharmacy access requirements as a minimum threshold for network adequacy.

NCPA would also recommend that Exchanges establish specific standards under which QHP issuers must establish an ongoing monitoring process to ensure the sufficiency of the network for enrollees. Such a monitoring program could include regular beneficiary surveys and should also require QHPs to implement certain remedial measures in order to boost beneficiary access if a network is found to be too restrictive.

Section 156.235 Essential Community Providers

The proposed rule requires QHP issuers to include in their provider networks a sufficient number of essential community providers, where available, that serve low-income, medically-underserved individuals. Independent community pharmacies in particular are frequently located in very rural or urban areas—communities that many times are not served by the traditional chain pharmacies. In addition, given their location in these areas, independent community pharmacies serve a greater portion of low-income individuals than chain pharmacies as well. Access to pharmacy services in general can prevent more costly downstream medical procedures and promote overall wellness. For that reason, QHP issuers should consider a potential safe-harbor strategy that would ensure access to essential community pharmacy providers in these and all areas and allow the participation of all “willing pharmacies” or those pharmacies that agree to accept the terms of the contract.

Section 156.295 Prescription Drug Distribution and Cost Reporting

Section 6005 of the ACA requires the disclosures listed under this Section and provides that a QHP issuer to provide to HHS information on the distribution of prescription drugs, pharmacy benefit management (PBM) activities, the collection of rebates and other monies in conducting these activities and costs incurred to provide those drugs.

Under this section QHP issuers must provide information to the Secretary of HHS on:

- The percent of all prescriptions provided through retail pharmacies compared to mail order and the generic dispensing rate and substitution rates of each;
- The aggregate amount and types of rebates attributable to patient utilization under the QHP and the aggregate amount of rebates passed through the QHP issuer and number of prescriptions dispensed;
- The aggregate amount of the difference between the amount the issuer pays its PBM and the amount the PBM pays retail and mail order pharmacies

These requirements are critical to ensure that the QHPs are receiving this necessary information from their PBM in order to better manage the drug benefit portion of the plan. In addition, without a baseline of meaningful transparency in the relationship between the PBM and health plans, it will be inherently difficult to accurately apportion PBM fees into medical/quality expenses versus administrative expenses for the purposes of compliance with the required medical loss ratio (MLR) calculation. It is only by requiring QHPs to extract this necessary data from the PBM that these issuers will be assured of their compliance with the MLR requirements of the Affordable Care Act.

NCPA Recommendations for Future Guidance Issued on This Section Include a Requirement that Disclosures be Provided in “Plain Language” and the Usage of Standardized Definitions

The Preamble to this proposed rule indicates that HHS anticipates the issuance of a guidance on the reporting of these data elements and also that HHS is seeking comment on potential definitions for “rebates,” “discounts,” and “price concessions” and that HHS is considering the appropriateness of using the term “direct and indirect remuneration.” NCPA feels strongly that guidance is needed in order to ensure that valid information is submitted in an understandable format and also that standardized definitions are critical in order to ensure that the data submitted by one QHP can be reliably compared to the data submitted by other QHPs.

NCPA would recommend that any such guidance require that the requisite information must be submitted—just as it is suggested in Section 156.220(a) on coverage transparency-- in “plain language.” The Preamble also states that the Secretaries of HHS and Labor will jointly issue guidance on “best practices of plain language writing.” (Preamble p.105). This will help to ensure that the extremely complex data elements routinely used in the PBM environment will be decipherable to all audiences.

Equally as important in ensuring the effectiveness and utility of the required disclosures, is the usage of standardized definitions. A routine criticism of the PBM industry and PBM contracting practices is the fact that there does not exist a standardized set of definitions used in this process. The majority of all of the litigation filed against the PBMs over the past decade has alleged that they are engaged in “rebate labeling” games—in which the PBM recharacterizes rebates as something seemingly benign such as “administrative fees” or “health management grants.”

The challenge is drafting regulatory language that will cover all of the collateral arrangements that PBMs have negotiated in connection with a particular plans’ drug utilization. In addition, many times PBMs also enter into contracts with wholesalers, distributors or other third parties. Most often, rebates are associated with brand name drugs; however, rebates can be associated with generic drug spending through the drug wholesalers. Many times, PBMs will not disclose these amounts because although they are indeed rebates, they are not “manufacturer rebates.”

NCPA strongly supports the usage of the suggested term “direct and indirect remuneration” as a definition for “rebates” to encompass all of the various arrangements through which PBMs derive compensation based on a plan’s drug spend. Much, if not the majority, of compensation that PBMs receive is in the form of indirect compensation. In light of this fact, NCPA would recommend the use of the additional clarification for “indirect compensation.”

- ***“Indirect compensation is compensation received from any source other than the plan, the covered service provider, an affiliate or subcontractor and shall include all financial benefits the PBM receives, including but not limited to all: rebates, discounts, credits, fees, grants, chargebacks, or other payments or financial benefits of any kind.”***

Finally, NCPA agrees with the interpretation that “PBM” should be defined to include any entity that performs such activities (prescription drug claims processing, negotiation with prescription drug manufacturers, the development and maintenance of pharmacy networks, or the distribution of prescription drugs on behalf of the health insurance issuer) on behalf of a QHP issuer, supports the codification of the confidentiality requirements and supports the codification of the penalties for noncompliance with this section.

Conclusion

As you gather information from all of the interested stakeholders in response to this Proposed Rule regarding Establishment of Exchanges and Qualified Health Plans, NCPA respectfully urges you to consider these issues. We appreciate the opportunity to share our thoughts and recommendations with you.

Sincerely,



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