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Submitted Electronically Via: FFEcomments@cms.hhs.gov

Center for Consumer Information and Insurance Oversight
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: 2015 Letter to Issuers in the Federally-facilitated Marketplace (FFM)

To Whom It May Concern:

The U.S. Chamber of Commerce (the "Chamber") submits these comments in response to the Draft 2015 Letter to Issuers in the Federally-facilitated Marketplace ("Draft 2015 Letter"), as issued on February 4, 2014 from the Center for Consumer Information and Insurance Oversight ("CCIIO") within the Centers for Medicare and Medicaid Services ("CMS"). Of the seven chapters in the Draft 2015 Letter, there are several areas of significant concern to the Chamber because of the significant impact that many of the proposed provisions would have on limiting choice, flexibility and variation in benefit plan design offerings on the Federally-facilitated Marketplace ("FFM"), or as statutorily defined Health Benefit Exchange. In limiting choice and flexibility, these restrictions will also increase costs by limiting the tools that issuers and employers have historically used to control costs. Finally, the Chamber finds many of the proposals in the Draft 2015 Letter to be beyond the scope of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively renamed the Affordable Care Act ("ACA").[1]

The Chamber is the world's largest business federation, representing the interests of more than three million businesses and organizations of every size, sector and region, with substantial membership in all 50 states. More than 96 percent of the Chamber's members are small businesses with 100 or fewer employees, 70 percent of which have 10 or fewer employees. Yet, virtually all of the nation's largest companies are also active members. Therefore, we are particularly cognizant of the problems of smaller businesses, as well as issues facing the business community at large. Besides representing a cross-section of the American business community in terms of number of employees, the Chamber represents a wide management spectrum by type of business and location. Each major classification of American business – manufacturing, retailing, services, construction, wholesaling, and finance – is represented. These comments have been

[1] The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152 (2010).

developed with the input of member companies with an interest in improving the health care system.

OVERVIEW

The Chamber urges CCIIO to consider the current status of implementation, ACA's statutory requirements and the authority it grants, as well as the very principles in the title of the law for which they are promulgating this sub-regulatory guidance. We remain concerned that given the challenges facing the FFMs now given the numerous and complex requirements specifically delineated under the law's provisions and the goals of affordable care and patient protection, many provisions in the Draft 2015 Letter will increase cost and harm patients.

I. CURRENT STATUS OF IMPLEMENTATION

With comments being reviewed by CCIIO now, at the end of February, we urge the Administration, HHS, CMS, and CCIIO to appreciate the challenges of this first year of the Marketplaces at both the state and federal level and recognize that we are merely a few months from the time when issuers must finalize their offerings for 2015. This first year of marketplace operation, both for individuals and for small businesses, has been exceedingly challenging. With the law's provisions changing many of the levers through which issuers have typically offered varied plan options, the headlines and stories of rate shock and confusion have been extensive. Before making additional changes, we urge CCIIO to adopt a more cautious approach that would allow careful analysis of the successes, failures and challenges for this first year before creating additional requirements in 2015.

Small Business Health Options Programs: Launching Employee Choice

Issuers and employers continue to experience a lot of uncertainty around implementation of the Small Business Health Options Program exchange ("SHOP"). States implementing SHOP continue to experience low enrollment. Even California recently announced it is suspending its on-line SHOP enrollment. Despite this nationwide uncertainty that is continuously strewn across the media, in the Draft 2015 Letter, CMS reiterates their requirements that all FFMs and state-based exchanges launch an automated shopping, enrollment and billing process for employee choice in under 9 months.

For 2014, employers were not able to shop and enroll in products for selection of a single Qualified Health Plan (QHP) via FFM. The basic employer choice shopping and enrollment functionality alone will take time to test and implement to ensure that employers have a seamless experience in applying, enrolling and paying for SHOP coverage. To make SHOP products available in 2014, issuers have had to implement manual processes to both enroll employers and report enrollments to CMS. In addition, employers who had applied to SHOP electronically had to start over in November and work directly with issuers.

Fulfilling the promise of an employee choice approach where employees can select among multiple QHPs will significantly broaden the scope and complexity of SHOP FFM implementation in 2015. In order for employee choice to work as intended, three information

technology systems (SHOP eligibility determinations, SHOP premium aggregator billing and payment, and QHP issuer enrollment systems) will have to work in sync and without error.

However, CMS has yet to provide an implementation timeline for automated shopping and enrollment, or for ensuring the effective orchestration necessary for employee choice. We are concerned that CMS may launch the SHOP employee choice approach without ensuring systems are tested, working and validated by issuers, employers, and SHOPs. Requiring the launch of all these features at the same time may replicate the negative experience consumers in individual Marketplaces are experiencing this year.

While the Chamber favors the ability for employers to choose to allow employee choice when offering coverage to their employees in the SHOP, we believe that requiring SHOP FFMs to implement this complicated offering in 2015 would be unwise. Just as CCIIO has adopted a more careful phase-in approach for 2014 where enrollment must be done directly with plans, issuers or brokers with no employee choice capabilities, we encourage CCIIO to move forward carefully in 2015. As HHS considers launching new capabilities for SHOP, HHS should continue to leverage the lessons learned from states that opted to implement employee choice. Based on the federal experience in launching employer choice in 2014, CMS should first ensure automated shopping and enrollment through SHOP is available for employer choice. We recommend CMS delay implementation of employee-choice until the functionality for the SHOP employer choice model is running smoothly, including the ability to process enrollments for employers and communicate them to issuers in an automated manner.

II. CONSIDER ACA GOALS AND STATUTORY LANGUAGE

Given the challenging first few months that providers, issuers, employers and individuals have had as the ACA's more significant provisions take effect in 2014, we urge the Administration to proceed cautiously and prudently. The Chamber has serious concerns from an implementation standpoint, from a statutory authority perspective and also from the policy standpoint of advancing affordability, choice and patient/consumer protection. In four specific topic areas, the Draft 2015 Letter proposes to impose additional requirements for 2015 which will be challenging to implement, as well as limit plan design, flexibility and affordability, all of which are not required under the statute.

The Draft 2015 Letter imposes worrisome new requirements on provider networks, prescription drug coverage, and primary care coverage. These limitations are concerning from a practical and substantive standpoint because they will limit the ability of issuers to offer a broader array of plans on the FFM and require issuers to include elements in terms of network, formulary and benefit design that are not required by law. This will make the variety of plans available more meager and will increase the cost of the most moderate plan by requiring more comprehensive network, formulary and benefit designs for all offerings.

Further, beyond the very real pragmatic problems with these new restrictions, the Chamber is extremely troubled by the improper regulatory power grab to create and impose such restrictions. There are no such statutory specifications that require coverage in FFMs to meet these prescriptive delineations and to unilaterally create and impose them is not only disconcerting, but

improper given the infancy of the FFM and the absence of any documented need for these sub-regulatorily created requirements.

A. New Network Adequacy Requirements

The Draft 2015 Letter imposes on page 19 new federal network adequacy review standards. In order for a QHP to be certified under the Draft 2015 Letter, the issuer must submit lists of all the QHP's in-network providers and facilities. Rather than relying on long-standing state review or accreditation processes (as CMS did in 2014), the Draft 2015 Letter gives CMS the authority to evaluate network adequacy using a new "reasonable access" standard that has yet to be defined.

1. UNNECESSARY

Employers and insurers must continue to have the flexibility to design benefits, plans and networks using the existing state network adequacy review process, provided those processes meet the final rule standards at 45 CFR. §156.230(a)(2). The standards already finalized in that rule require a QHP insurer to maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to assure that all services will be accessible without unreasonable delay. While we do not believe CMS should assume the states' role in this process, we believe that the current monitoring that CMS conducts over the state review of network adequacy through, for example, complaint tracking and other means is appropriate and sufficient.

There are many safeguards in place to ensure that consumers have a variety of high-value choices when selecting an insurance product. As mentioned, current state processes require all plans regardless of their network size or configuration, to satisfy the state's network adequacy standards, and meet network adequacy requirements established by the private accrediting organizations that accredit FFM plans. Furthermore, plans are subject to state market conduct examinations that review, among other areas, network adequacy. Additionally, CMS will continue to monitor network adequacy via complaint tracking and other means.

2. FEDERAL OVERREACH

If finalized as proposed, the new network requirements delineated in Chapter 3 will unnecessarily expand the regulatory reach of the federal government and improperly usurp the appropriate regulatory authority of states as intended by the ACA. Every QHP network is currently subject to approval and oversight by state insurance commissioners and private accreditors, and monitoring by CMS. Layering an additional federal review process onto the certification process will not only delay QHP certification and create a duplicative and burdensome regulatory scheme, but could have a harmful impact on cost for consumers.

3. UNDERCUTS ACA GOALS: LIMITS CONSUMER CHOICE AND HARMS AFFORDABILITY

Further, CMS proposes issuing future rules on how it may use the information obtained during the federal review process to create additional time and distance requirements for assessing FFM networks. We are loath to see any additional prescriptive standards on network design in the FFM, and would instead recommend careful assessments are done on this year's networks and if

necessary, based on actual access problems, future modifications should be evaluated in the context of the increased costs those standards will add for products. There are already a myriad of constraints on how premiums and out-of-pocket costs and copayments are set, as well as the types of benefits that must be covered in the small group and individual markets. The Chamber urges CCIIO and CMS to wait before imposing any additional requirements that will impact the affordability of products in these markets. Any necessary future guidance must not further restrict flexibility and design variation by imposing additional one-size-fits-all requirements that limit choice and competition and increase the cost of premiums.

By permitting variations in network design, exchanges can provide a greater array of plan choices, many with more affordable premiums to better meet the preferences of consumers and small businesses. According to McKinsey, while there are no quality differences among different networks, consumers in smaller networks pay less on average premiums.[2] With plans options that include smaller and/or tiered networks, consumers can actually enjoy greater value by obtaining treatment from high-performing providers, or by implementing delivery innovations, such as patient-centered medical homes and Accountable Care Organizations (ACOs).

B. Transitional Coverage of Non-Formulary Drugs

The Draft 2015 Letter proposes on page 33 to require in future rulemaking that FFM plans temporarily cover non-formulary drugs to new enrollees. CMS suggests that future rulemaking may require issuers to immediately cover all drugs on their formulary for the first 30 days of coverage regardless of the plan's prior authorization or step therapy processes for coverage beginning on January 1 of each year, starting with the 2015 plan year. The Chamber recommends that CMS not issue any requirement for temporary coverage of non-formulary drugs in rulemaking or guidance.

1. UNNECESSARY

There are already a variety of mechanisms in place to address enrollees' need for non-formulary drugs when coverage beings, such as exceptions and appeals processes. Insurers use these same mechanisms and best practices for plans offered on the FFM as they do for their other lines of business, including employer group coverage. These mechanisms have long been in place to meet the needs of the employees and employers of groups who also change insurers periodically and are already provided for enrollees through the FFM.

Although the proposed transition policy mirrors the policy in Medicare Part D, important differences between Part D plans and QHPs render this policy unnecessary in FFM plans. First, when consumers enroll in a QHP, they can select a QHP based on drug formulary placement, if that is important to them. Second, QHP enrollees are not be subject to the same automatic disenrollment and re-enrollment in different prescription drug plans, based on plans' bids in relation to the national benchmark as many Part D enrollees are.

Historically, a similar transition period of coverage when offered by a plan for new enrollees ultimately created more problems than it solved. The policy was too confusing (enrollees didn't

[2] McKinsey Report, Hospital Networks: Configurations on the exchanges and their impact on premiums, 2013.

understand why the drug was covered, and then why the coverage was dropped). It also created safety issues as enrollees were eventually forced to change medications quickly, rather than transition to new a medication as they should have. Members must ultimately pursue the exceptions process, or must transition to an appropriate formulary drug, and very little is gained by prolonging the transition.

2. FEDERAL OVERREACH

Furthermore, CMS has not demonstrated the need for this new requirement which will likely be quite expensive for plans to implement and increase enrollee costs. The Chamber would urge CMS and CCIIO to assess the experience of new enrollees before mandating such a dramatic and costly type of transition coverage.

Operationally, developing a new prescription drug transition process now is not feasible, because prescription drugs are generally adjudicated at the point-of sale. Pharmacists cannot be expected to set up a separate, manual process for adjudicating claims for new QHP members. Further, it would be difficult and expensive to reprogram systems to recognize and adjudicate these special pharmacy claims only for the first 30 days.

3. UNDERCUTS ACA GOALS: JEOPARDIZES PATIENT SAFETY

There could be adverse clinical effects resulting from the transition policy. Coverage of all drugs that a new health plan enrollee may be taking at the time of enrollment may violate clinical standards and protocols adopted by a plan for safety and quality of patient care purposes, which is often the reason for imposing a prior authorization requirement. As a result, QHPs may be unable to maintain such standards and protocols during the transition period.

By effectively suspending all formulary and drug benefit management requirements during the first month of a new enrollee's transition to a QHP, a health plan could be prevented from acting in situations of potential fraud and abuse, particularly with regard to opioids and other medications with a high risk for over-use and abuse.

We agree that any changes to the prescription drug requirements must be done through notice-and-comment rulemaking. However, we are extremely concerned that by the time the formal rulemaking process is completed, the time will be too short and insufficient for carriers to effectively adjust the pricing and design of their benefits for plans offered in 2015. Because the operational issues are sufficiently complex, promulgating a comprehensive transition policy in time for the 2015 plan year may not be feasible.

C. Primary Care Coverage

The Draft 2015 Letter on page 38 states that CMS may require, or at least strongly encourage, all plans or at least one plan at each metal level per issuer to cover three primary care office visits before the deductible on the FFM. This requirement is above and beyond even what the Essential Health Benefit provision requires under the ACA and if implemented, would increase the cost of plans, limit choice and potentially eliminate certain plan designs highly valued by individuals and small businesses alike.

1. *UNNECESSARY*

This new unilaterally imposed benefit mandate is unnecessary. All QHPs are required to provide zero dollar cost sharing for all essential health benefits which include preventive and wellness services. Under most state benchmarks, this category includes an annual physical. Before imposing this new coverage requirement, we would urge CMS to first assess the use of QHPs and data available in 2014 and then adequately document the need for such a significant modification.

2. *FEDERAL OVERREACH*

This new mandate would eliminate the ability of High Deductible Health Plans (HDHPs) to be offered on the FFM. There is nothing in ACA that suggests an intent or desire to eliminate this benefit design and valued product and there is nothing in the essential health benefit provision that requires this type of coverage for primary care office visits. Given that there is no language in the ACA to limit the use of Health Savings Accounts with HDHPs, CMS has no express authority to be regulating in this particular area of benefit design. HSAs were originally authorized by Congress by the Medicare Prescription Drug Improvement and Modernization Act of 2003 with the intent of engaging consumers in the purchase of health care services.[3] CMS should not be regulating via this sub-regulatory letter in areas of benefit design where Congress did not give them express authority.

Moreover, CMS is prohibited from mandating benefits in this way without notice-and-comment rulemaking. Under the ACA, the Secretary of HHS has the authority to define "essential health benefits."[4] The Secretary exercised that authority by selecting a benchmark approach for defining "essential health benefits."[5] If the Secretary wants to further mandate benefits, she would need to amend the essential health benefit rule; additional mandated benefits are a fundamental change to the existing requirements.

4. *UNDERCUTS ACA GOALS: LIMITS CONSUMER CHOICE AND HARMS AFFORDABILITY*

Benefit and plan design flexibility is paramount to ensuring that there are a variety of products available at a broader range of costs. To require all plans offered on the FFM to cover three primary care office visits prior to an enrollee meeting any deductible will limit the ability of various plans to keep coverage affordable. Most significantly, this requirement will prohibit the offering of Health Savings Account qualified health plans which are popular options for both employers and individuals as they encourage consumers to be more conscious of medical-care costs and more cautious about undergoing unnecessary expensive procedures, thus driving down costs for employers. HSAs and HRAs are popular options for both employers and individuals. By encouraging consumers to be more conscious of medical-care costs and more cautious about undergoing unnecessary expensive procedures, these options drive down costs for employers. The percentage of workers enrolled in either type of high-deductible plan, a HSA or a HRA has

[3] Internal Revenue Code § 223.
[4] Pub. L. 111-148, title I, §1302, title X, §10104(b), Mar. 23, 2010, 124 Stat. 163, 896
[5] Standards Related to Essential Health Benefits, Actuarial Value and Accreditation, Final Rule, 78 Fed. Reg. 12,834- 12,872 (February 25, 2013) (to be codified at 45 C.F.R. pts. 156.100-156.150).

quadrupled since 2006 and by 2012, 31 percent of small employers with 3 to 199 employees offered either an HRA or HSA eligible plan.[6] We urge CMS to drop this language from the Draft 2015 Letter in order to preserve a valued benefit offering and other affordable coverage options.

CONCLUSION

We encourage CMS and CCIIO to continue to work carefully, pragmatically and cooperatively with the numerous stakeholders to minimize unnecessary costs for, and burdens on, employers and provide flexibility as employers work to comply with the law. We look forward to continuing to work together in the future.

Sincerely,

Randel K. Johnson
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Katie Mahoney
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[6] Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2012.