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Donald M. Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Patient Protection and Affordable Care Act (ACA); Establishment of Consumer Operated and Oriented Plan (CO-OP) Program (File Code CMS-9983-P)

Dear Administrator Berwick:

On behalf of our physician and medical student members, the American Medical Association (AMA) greatly appreciates this opportunity to provide comments in response to the proposed rule entitled "Patient Protection and Affordable Care Act (ACA); Establishment of Consumer Operated and Oriented Plan (CO-OP) Program" (Proposed Rule), published in the Federal Register July 20, 2011.

Section 1322(a) of the ACA requires the Secretary of Health and Human Services (HHS) to establish the CO-OP Program. Operating as nonprofit organizations, CO-OPs will compete directly with established nonprofit and profit-seeking health insurers in the state-based health insurance exchanges and small business exchanges created under the ACA. As emphasized in the AMA's March 4, 2011, response to HHS' Request for Comments Regarding Provisions of Consumer Operated and Oriented Plan Program, published February 2, 2011, private health insurance markets are not competitive, as entry barriers have enabled large incumbent health insurers to remain profitable and maintain if not increase their dominance in most, if not all, health insurance markets for years. CO-OPs could, however, inject desperately needed competition into those markets. Accordingly, in its March 4 correspondence, the AMA urged CMS to interpret and apply the provisions of Section 1322 flexibly so as to facilitate CO-OP formation and entry.

CO-OPs will be entering a highly complex market that will require a broad array of technical skills. A successful CO-OP will need the following skills in addition to the basic insurance functions of collecting premiums and paying claims: disease management, wellness and prevention management, utilization and care management, and quality of care management. In considering these requirements, the challenges are enormous for anyone who has never been involved in health care. To put it simply, most individuals, even the most talented entrepreneurs, do not have the skills to run a CO-OP and compete against private insurers. But these skills are not exclusive to representatives of incumbent insurers. Physicians deal with these issues on a daily basis. They are ideally positioned to take a lead role in establishing and managing CO-OPs and, unlike representatives of incumbent insurers,

physicians are *not* among those listed in Section 1322 (e) as being prohibited from serving on the board of directors (and therefore, under principles of statutory construction, physicians are permitted to assume roles on the governing board). Moreover, physician board membership and leadership would give the physicians a stake in the competitive success of the CO-OP. They may therefore be expected to: (i) foster CO-OP marketing through testimonials offered to patients; (ii) develop an efficient provider network that would lower costs; and (iii) discount physician fees to levels that would enable the CO-OP to successfully enter a market dominated by large established insurers extracting large discounts because of their market shares.

The AMA applauds CMS for its commitment in the Proposed Rule to apply Section 1322 flexibly. The Proposed Rule also represents a serious attempt to ensure that CO-OPs will be new, independent players in health insurance markets rather than foils for incumbent, dominant health insurance issuers. At the same time, the AMA believes that a few portions of the Proposed Rule merit clarification. The AMA is also concerned that the Proposed Rule may not afford the CO-OP Program with safeguards sufficient to ensure that sponsors, applicants, qualified nonprofit health insurance issuers, and CO-OPs represent new health insurance issuers that are truly independent of pre-existing health insurers and related entities.

CMS should expand the Proposed Rule to ensure that only organizations that are truly independent of pre-existing health insurance issuers are eligible to be applicants.

The Proposed Rule will not achieve the underlying purpose of Section 1322 unless the rule restricts CO-OP Program assistance to organizations that are truly independent of, and represent real alternatives to, pre-existing health insurance issuers and related entities. To ensure this independence, CMS should expand the Proposed Rule to prohibit the entities identified in proposed 42 CFR § 156.510(b)(1)(i) from sponsoring an applicant and ensure that applicants are otherwise free from the influence of those entities. Ensuring that applicants are wholly independent from pre-existing health insurance issuers and related entities will not disadvantage those issuers or entities. Pre-existing health insurance issuers and related entities are likely to have the financial resources sufficient to create a new health insurance market entrant. Therefore, such an entrant's need for federal assistance is not nearly as acute as an organization that does not receive funding from the health insurance industry. Also, providing federal assistance to pre-existing health insurance issuers or related entities endeavoring to develop new lines of business is contrary to the goal of Section 1322. Finally, it is unclear whether many pre-existing health insurance issuers would be truly committed to the success of any applicant they sponsored, since applicants would ultimately compete against those issuers in the health insurance markets in which those issuers operate.

CMS should prohibit pre-existing health insurance issuers, related entities, or the predecessors of either, from sponsoring or being in a position to influence an applicant.

The AMA believes that there is significant ambiguity regarding the scope of sponsorship in the Proposed Rule. The Proposed Rule's definition of "sponsor" contains no restrictions, since "sponsor" is defined as "an organization or individual that is involved in the development, creation, or organization of the CO-OP or provides financial support to a CO-OP." 76 FR 43248. Proposed 42 CFR § 156.510(b)(1)(i) also does not appear to place any restriction on the types of entities that may sponsor an applicant. That proposed standard simply states that the following are not permitted "to apply" for a CO-OP loan:

(1) a pre-existing issuer;
(2) a predecessor of a pre-existing issuer;
(3) a trade association whose members consist of pre-existing issuers;
(4) a related entity; or
(5) a predecessor of a related entity.

However, the preamble to the Proposed Rule distinguishes between "sponsors" and the nonprofit member corporations that are eligible to participate in the CO-OP program. For example, the preamble contains the following statement:

> CMS proposes the applicant have formed a nonprofit member organization under State law prior to applying for a loan. This means that the new nonprofit member corporation, and not an organization that is sponsoring the creation of a CO-OP, would be the applicant for and recipient of a loan.

76 FR 43241-43242. Based on this statement, it appears that proposed 42 CFR § 156.510(b)(1)(i) prohibits pre-existing issuers, related entities, and their respective predecessors, from being applicants. The prohibition, however, does not appear to extend to applicant sponsors.

We believe, however, that other portions of the Proposed Rule can be interpreted as reflecting CMS' desire to limit the types of entities that may serve as sponsors. For example, in a discussion concerning related entities, CMS states in the Preamble:

> CMS would permit a nonprofit organization that is not an issuer or the representative of an issuer but shares control with an existing issuer to "sponsor" or facilitate the creation of a CO-OP if the applicant (and resulting CO-OP) and the existing issuer do not share the same chief executive or any of the board of directors.

76 FR 43241. See also proposed 42 CFR § 156.510(b)(2)(i). Additionally, in a discussion concerning examples of entities that are not "issuers," CMS states:

> CMS believes that the following types of entities are examples of organizations that are not 'issuers' and would be eligible to sponsor applicants for loans under the CO-OP program provided that they otherwise meet the requirements for eligibility….

76 FR 43242. Statements such as these could be interpreted as evidencing CMS' intention to limit the types of organizations that are permitted to sponsor a CO-OP. The AMA urges CMS to adopt such an interpretation, with the additional limitations described below.

The CO-OP Program's efforts to effectuate the aims of Section 1322 will be compromised unless sponsors and applicants are wholly independent of pre-existing health insurance issuers and related entities. Thus, any final regulations adopted by CMS should prohibit:

(1) any sponsor or applicant from receiving loans or other financial benefit from a pre-existing health insurance issuer or related entity;
(2) any individual who is employed by, on the board of, or an officer of, any pre-existing health insurance issuer or related entity from occupying a management position in the sponsor or applicant;
(3) any individual who is employed by, on the board of, or an officer of, any

pre-existing health insurance issuer or related entity from occupying a position on the governing board of a sponsor or applicant; or

(4) any individual holding more than one percent of the equity in a pre-existing health insurance issuer or related entity from occupying a management position in, or a position on the governing body of, a sponsor or applicant.

The AMA believes that such restrictions are essential to implement Section 1322's underlying purpose. The competition envisioned by Section 1322 will only occur if the CO-OP Program results in the entry of issuers that are truly "new" to the health insurance market. Applicants and sponsors that are not wholly independent of pre-existing health insurance issuers and related entities hardly represent new entrants or real alternatives. Moreover, allowing applicants and sponsors with ties to the insurance industry to receive federal assistance would divert limited funds from those qualified applicants that have the most potential to reintroduce competition.

Moreover, excluding pre-existing health insurance issuers, related entities, and entities over which they possess influence will not disadvantage those organizations. Such organizations, particularly those enjoying market dominance, already possess the financial resources sufficient to create new market entrants. Additionally, most pre-existing health insurance issuers will have little, if any, interest in sponsoring an applicant, as any bona fide applicant would ultimately compete against the issuer in its health insurance market.

CMS should expand the definition of "related entity."

For the same reasons we urge CMS to limit the entities that can be sponsors, the AMA believes that CMS must expand the definition of "related entity." The Proposed Rule defines "related entity" as an entity that:

(A) shares common ownership or control with a pre-existing issuer or a trade association whose members consist of pre-existing insurers; **and**
(1) retains responsibility for the services to be provided by the issuer; ***or***
(2) furnishes services to the issuer's enrollees under an oral or written agreement; ***or***
(3) performs some of the issuer's management functions under contract or delegation.

The Proposed Rule's conjunction of the common ownership or control requirement of (A) with requirements (1), (2), or (3) results in a definition of "related entity" that is not sufficiently broad. The definition is too narrow to ensure that CO-OP Program funds will be used solely to facilitate entry of CO-OPs that are truly independent of pre-existing health insurance issuers. For example, given this definition, the proposed exclusion in 42 CFR § 156.510(b)(1)(i) would allow a pre-existing health insurance issuer to create an applicant with respect to which the issuer could share common ownership or control, so long as the applicant did not qualify as a related entity by also engaging in (1), (2), or (3) above. Additionally, 42 CFR § 156.510(b)(1)(i)'s exclusion with regard to "predecessors" would be inapplicable because the applicant would be neither a related entity nor a pre-existing health insurance issuer. Consequently, the proposed definition and its use in proposed 42 CFR § 156.510(b)(1)(i) would compromise Section 1322's goal of fostering the entry of new competitors unalloyed with dominant insurers.

The definition of "related entity" must, therefore, be broadened. To this end, the AMA urges CMS to adopt the following definition of "related entity" in any final rule:

"Related entity" means an entity that:

(1) shares common ownership or control with a pre-existing issuer or a trade association whose members consist of pre-existing insurers; ***or***
(2) retains responsibility for the services to be provided by the issuer; ***or***
(3) furnishes services to the issuer's enrollees under an oral or written agreement; ***or***
(4) performs some of the issuer's management functions under contract or delegation.

This definition is critical to achieving the goals of Section 1322 for two reasons. First, by placing an "or" between (1) through (4), an applicant that shares common ownership or control with a pre-existing health insurance issuer is excluded from participating in the CO-OP Program, regardless of whether or not the applicant also performs the functions described in (2), (3) or (4). Second, the definition also ensures that any entity satisfying the requirements of (2), (3), or (4) is a related entity, irrespective of considerations of common ownership or control. This second reason is just as important as the first in terms of effectuating the purpose of Section 1322. Entities performing activities described in (2), (3), or (4) are not new entrants, nor are they likely to be able to achieve independence from the dominant insurers whose business they cannot afford to do without. Final adoption of the AMA's suggested definition is therefore essential to ensure that the CO-OP Program achieves Section 1322's aims.

Exclusion of multiple employee welfare arrangements (MEWAs) from the definition of "issuer."

In the preamble to the Proposed Rule, CMS states that the following entities are excluded from the definition of "issuer:"

(1) a prospective applicant not licensed by its State as a health insurance issuer on July 16, 2009, but which has subsequently achieved a State license;
(2) self-funded and Taft-Hartley group health plans; and
(3) church plans that were not licensed issuers on July 16, 2009; and
(4) three-share or multi-share programs not licensed by their State insurance regulator.

76 FR 43242. The AMA believes that MEWAs and their affiliates should be included within the class of entities that are excluded from the definition of "issuer." Permitting MEWAs and their affiliates (whether formed prior to or after the enactment of the ACA) to function as applicants or sponsors will not undermine the purposes of Section 1322, since MEWAs typically do not occupy positions of dominance in health insurance markets. MEWAs also are not "related entities" as defined in the Proposed Rule. Nor will MEWAs often, if at all, be predecessors to pre-existing health insurance issuers or related entities. MEWAs also possess the skeletal infrastructure, provider network, and beneficiary and small employer focus to develop into robust competitors with the aid of the capital from Start Up and Solvency Loans. There should, therefore, be no restrictions on MEWAs serving as applicants or sponsors.

Concerns about the breadth of proposed 42 CFR § 156.510(b)(2)

The AMA has serious concerns regarding the scope of 42 CFR §156.510(b)(2). This provision, dealing with eligibility, provides two exceptions to the general exclusion contained in 42 CFR § 156.510(b)(1)(i). One exception, described in 42 CFR §156.510(b)(2)(i), states that the exclusion in 42 CFR § 156.510(b)(1)(i) does not apply to an applicant where one of the applicant's

sponsors is a nonprofit organization that also sponsors a pre-existing health insurance issuer, so long as:

> (1) the sponsoring nonprofit organization is not a health insurance issuer; and
> (2) the sponsored, pre-existing health insurance issuer does not share any of its board or the same chief executive with the applicant.

The AMA believes that CMS should not adopt the 42 CFR § 156.510(b)(2)(i) exception as written. Even if the applicant does not share the same CEO or board with the pre-existing health insurance issuer, it is likely that this sharing prohibition will not adequately insulate the CO-OP from influence by either the pre-existing health insurance issuer or that issuer's affiliated nonprofit organization sponsor. For example, through their corporate affiliation, the pre-existing health insurance issuer and the applicant might share key personnel other than the chief executive or board members. Further, the applicant may naturally be inclined and encouraged to adopt the same business practices, e.g., provider contracting, reimbursement, claims processing, eligibility determination, benefit plan design, etc., used by the health insurance issuer. It is also likely that the applicant would look to the affiliated nonprofit sponsor or pre-existing health insurer for expertise whenever the applicant confronts a challenge regarding its business or insurance operations. Even though the pre-existing health insurance issuer might not be able to directly control the conduct of the applicant, it is likely that the applicant's conduct will be significantly influenced by a health insurance issuer that is a member of the applicant's corporate family. The AMA believes that this result is inconsistent with Section 1322.

The AMA also believes that CMS should not adopt proposed 42 CFR §156.510(b)(2)(ii), which describes a second exception to the general exclusion contained in 42 CFR § 156.510(b)(1)(i). Under 42 CFR §156.510(b)(2)(ii), the general exclusion would not apply to an applicant that "has purchased assets from a pre-existing issuer provided that it is an arm's-length transaction where neither party was in a position to exert undue influence on the other." This exception, as written, might enable interested pre-existing health insurance issuers to circumvent statutory safeguards. This is because 42 CFR §156.510(b)(2)(ii) places no limit on the value of the assets that may be purchased. Under this exception, then, it appears that a pre-existing health insurance issuer could convey all of its assets to an applicant. The resulting applicant would not differ substantially from the pre-existing health insurance issuer that preceded the applicant. Accordingly, the AMA urges CMS to either drop 42 CFR §156.510(b)(2)(ii) from the final rule or include a limit on the value and percentage of the pre-existing health insurance issuer's assets that may be purchased, e.g., less than ten million dollars or 10 percent.

CO-OP standards

Governance requirements

The AMA generally supports the CO-OP standards described in proposed 42 CFR § 156.515. The AMA strongly urges CMS to adopt proposed 42 CFR § 156.515(b)(2)(iii), because permitting a CO-OP board to designate specific board seats for individuals with specialized expertise, e.g., community health care providers, is essential for CO-OP success. Although proposed 42 CFR § 56.515(b)(2)(iv) states that positions on the operational board that are designated for individuals with specialized expertise cannot constitute a majority of the operational board even if the individuals in those positions are members of the CO-OP, the AMA welcomes the further qualification that 42 CFR § 156.515(b)(2)(iv) does not prevent any individual from seeking election to the operational board based on being a member of the CO-OP. The AMA also strongly encourages final adoption of

proposed 42 CFR § 156.515(b)(2)(v), which prohibits a representative of a pre-existing health insurance issuer, a related entity, or a predecessor of a pre-existing health insurance issuer or related entity, from serving on the CO-OP's formation board or operational board.

The AMA seeks clarification concerning proposed 42 CFR § 156.515(b)(1)(iii). This provision states that each member of the organization must have one vote in the elections of the directors of the organization's operational board. This provision could be interpreted to unnecessarily limit voting for directors. For example, if several board seats in an organization were simultaneously up for election, and there were several nominees for each seat, this standard could be interpreted to mean that a member could only vote for one director in such an election, rather than for one director for each board seat. The AMA believes that the standard should be clarified so that each member would be able to cast one vote for each board seat that is contested during an election.

The AMA supports the distinction between the formation board and operational board. In particular, the AMA believes that proposed 42 CFR § 156.515(b)(2)(v), which permits any persons to serve on the formation board other than a representative of federal, state, or local government or a representative of any organization excluded from eligibility under 42 CFR § 156.510(b)(1)(i), is an excellent means of encouraging the maximum involvement of interested parties while at the same time minimizing the potential for health insurance issuer interference.

Standards for health plan issuance

The AMA strongly supports CMS' interpretation of the "substantially all" requirement of Section 1322(c)(1)(B) in proposed 42 CFR § 156.515(c)(1). This standard would interpret "substantially all" to mean that at least two-thirds of the policies or contracts for health insurance coverage issued by a CO-OP in each state in which it is licensed must be CO-OP qualified health plans offered in the individual and small group markets. The AMA urges CMS to adopt this interpretation in the final rule, as failure to interpret "substantially all" in terms of contracts or policies (as opposed to members) would preclude a great many interested organizations from having an opportunity to qualify under the CO-OP Program and provide the actuarial soundness that is critical to the success of the CO-OP and the protection of the related federal investment.

The AMA believes that it would be helpful for CMS to clarify what effect, if any, proposed 42 CFR § 156.515(c)(3) may have outside Exchanges. This proposed standard states in part that "Loan recipients may only begin offering plans and accepting enrollment in the Exchanges for new CO-OP qualified health plans during the open enrollment period for each applicable Exchange." Similar limits should not be imposed with respect to loan recipients' activities outside of Exchanges, and the AMA interprets the quoted language as imposing no such limits. The AMA requests clarification concerning whether its reading of the quoted language is correct. This issue is particularly important because some CO-OPs that have close relationships with clinically integrated providers may wish to offer early versions of their products to employees and purchasers outside of Exchanges.

Requirements to become a CO-OP

The AMA appreciates CMS' acknowledgment that applicants may require a significant amount of lead time before they are able to satisfy all of the CO-OP Program's standards. Proposed

42 CFR § 156.515(d) would afford an applicant 54 months following the draw down of Start-Up loans, or 18 months following the initial drawdown of Solvency loans, to satisfy all CO-OP standards. The AMA supports these deadlines and hopes they will be adopted in the final CO-OP Program rule.

State-wide scope

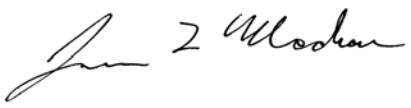
The AMA urges CMS to adopt a flexible, state-by-state application of the requirement that priority with respect to loan awards will be given to applicants that will offer qualified health plans on a statewide basis. Prioritizing and favoring applicants based on the statewide criterion at the beginning stages of CO-OP formation or operation will threaten the success of the CO-OP Program by significantly reducing the number of potentially promising applicants. Instead, priority should be based on an applicant's demonstrable commitment to operations occurring on a statewide basis. Additionally, CMS should apply the statewide criterion on a case-by-case basis, because there may be a number of states, e.g., California, Arizona, New York, and Texas, where requiring a CO-OP ultimately to cover an entire state may be impractical and unnecessarily limit the pool of otherwise qualified applicants.

Reinsurance or risk pool

The AMA reiterates a key concern expressed in our March 4, 2011 correspondence, namely, that CMS develop a mechanism that will assist CO-OPs' ability to spread risk adequately. Such a mechanism is critical, particularly in the early years of CO-OP operation. Historically, a number of physician-sponsored CO-OPs failed because of adverse selection resulting from physicians' commitment to providing needed care to vulnerable patient populations that were unable to obtain coverage from other sources. Possible mechanisms might include a national CO-OP risk pool or a federally-funded CO-OP stop-loss or reinsurance program. Purchasing council involvement could help facilitate the development of the needed risk-spreading mechanism.

Thank you for considering our comments. If you have any questions regarding this letter, please contact Margaret Garikes, Director of Federal Affairs, at 202-789-7409 or margaret.garikes@ama-assn.org.

Sincerely,



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