



May 26, 2011

Centers for Medicare & Medicaid Services, Department of Health and Human Services  
Attention: CMS-1345-P, P.O. Box 8013  
Baltimore, MD 21244-8013

**RE: CMS-1345-P**  
**Comments on Proposed Rules Relating to Section 3022 of the Affordable Care Act Relating to Accountable Care Organizations**

To Whom It May Concern:

On behalf of the Chief Justice Earl Warren Institute on Law and Social Policy, Health, Economic & Family Security program, at the UC Berkeley School of Law (“Warren Institute”), we write in response to CMS Release No. 1345-P, in which the Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services (HHS) solicited comments on its proposed rules implementing section 3022 of the Patient Protection and Affordable Care Act (“Affordable Care Act”) which contains provisions relating to Medicare payments to providers of services and suppliers participating in Accountable Care Organizations (ACOs).<sup>1</sup>

These comments will also serve as our response to:

- the Waiver Designs in Connection With the Medicare Shared Savings Program (MSSP) and the Innovation Center jointly published by CMS and Office of the Inspector General, HHS;
- Internal Revenue Service Notice 2011-20 on the MSSP;
- the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the MSSP published by the Federal Trade Commission and the Antitrust Division of the Department of Justice; and
- the Center for Medicare & Medicaid Innovation (CMMI)’s more recent proposals for an Advance Payment Initiative and Pioneer Accountable Care Organization Model.

The Warren Institute is a multidisciplinary, collaborative venture to produce research, research-based policy prescriptions, and curricular innovation on the most challenging civil rights, education, criminal justice, family and economic security, immigration and healthcare issues facing California and the nation. The Warren Institute is engaged in multiple projects concerning the implementation of health care reform and specifically working, under a twelve month grant from the Blue Shield

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<sup>1</sup>*Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations*, 76 Fed. Reg. 19528-01 (proposed Mar. 31, 2011) (to be codified at 42 C.F.R. pt. 425) [hereinafter “ACO Proposed Regulations”].

Foundation of California, on “Breaking Down Barriers to Creating Safety Net Accountable Care Organizations.” This joint project with the University of California, Berkeley’s School of Public Health has been funded to examine barriers to safety net ACO formation. It is in this capacity that we write to share our views.

Safety net health care providers and the populations they serve should be prioritized as participants in the proposed implementation of the Medicare Shared Savings Program. We write because we are concerned they are not. We are persuaded that there is untapped potential within the framework of the Accountable Care Act to foster creation of a safety net delivery system-sponsored ACO model.

The health care safety net has no standardized definition, a legacy of its lack of formal structure.<sup>2</sup> “Generally, though, the safety net includes public hospitals and health systems, health care districts, community health centers and clinics, and for-profit and nonprofit health care organizations that provide free or discounted care.”<sup>3</sup> In California, numerous indicators point to the fact that safety net providers serve a significant portion of our Medicare population. It is estimated, as of 2009, that 4.2 percent of California’s total Medicare patient coverage is delivered in community clinics alone.<sup>4</sup> In addition, we know that in 2006, the Medicare Part B program accounted for approximately ten percent of total net patient revenue for licensed primary care clinics in California.<sup>5</sup> And community clinics in California provided health care services to nearly 199,000 patients via Medicare Part B in 2008, accounting for approximately 6 percent of total clinic revenues that year.<sup>6</sup>

While we are pleased that CMS has acknowledged the special role of the health care safety net in providing health care to some of Medicare’s most underserved beneficiaries,<sup>7</sup> we offer comments to urge CMS to more fully support safety net providers in forming ACOs. Safety net health care providers serve a Medicare population that is both more complex and more expensive than the general Medicare population. This is a population ripe for integrated care innovation. We are heartened that CMS has prioritized monitoring of avoidance of at-risk patients<sup>8</sup> and prioritized rewarding those who serve the most complex Medicare beneficiaries.<sup>9</sup> It is apparent the safety net Medicare population represents both an opportunity and a challenge for CMS as it advances the Affordable Care Act’s goals.

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<sup>2</sup> Elizabeth Saviano, California Healthcare Foundation, California’s Safety-Net Clinics: A Primer 2 (2009), available at <http://www.chcf.org/~media/Files/PDF/S/PDF%20SafetyNetClinicPrimer.pdf>.

<sup>3</sup> *Id.*

<sup>4</sup> OSHPD, 2009 Annual Utilization Data for Primary Care Clinics ([http://www.oshpd.ca.gov/hid/Products/Hospitals/Utilization/PC\\_SC\\_Utilization.html](http://www.oshpd.ca.gov/hid/Products/Hospitals/Utilization/PC_SC_Utilization.html)) [hereinafter OSHPD data].

<sup>5</sup> Saviano, *supra* note 2, at 20, citing *California Community Clinics: A Financial Profile*, Analysis of 2003-06 Annual Utilization Data compiled by OSHPD. Capital Link, in collaboration with California Healthcare Foundation, November 2008.

<sup>6</sup> Capital Link, California Healthcare Foundation, California Community Clinics A Financial Profile, 2005-2008 37 (2010), available at <http://www.caplink.org/resources/California%20Community%20Clinics,%202005-2008.pdf>.

<sup>7</sup> ACO Proposed Regulations at 273.

<sup>8</sup> 42 CFR Section 425.12(b).

<sup>9</sup> *See, e.g.*, 42 CFR Section 425.7(b)(4).

In the comments below, we provide support for the following recommendations:

- Include FQHCs and RHCs in ACO formation
- Alleviate operational requirements that disproportionately burden safety net providers, including cost, administrative and patient barriers
- Ensure proper checks and balances on provider concentration in safety net ACOs
- Provide financial incentives tailored to safety net ACOs
- Supply safety net ACOs with technical assistance on issues such legal barriers and health privacy
- Consider the impact of ACO regulations on smaller safety net ACOs
- Engage state policymakers and stakeholders on possible state barriers to MSSP participation by safety net providers

### **I. Providers and Suppliers Eligible to Form an ACO: The Exclusion of FQHCs and RHCs**

Under the proposed rules, Federally Qualified Health Centers (“FQHCs”) and Rural Health Centers (“RHCs”) are ineligible to form ACOs<sup>10</sup> because each fails to collect data the rules identify as essential to the ACO assignment methodology. Specifically, data identifying the precise services rendered, the type of practitioner providing the services, and the physician specialty involved are not compiled.

**Data Issues.** FQHCs run afoul of the proposed rules because of a lack of a primary care Health Care Common Procedure Coding System (“HCPCS”), rendering the data inadequate for associating the rendering provider with the specific services furnished to the beneficiary.<sup>11</sup> The lack of the data elements necessary to determine beneficiary assignment during the performance year is based on CMS’s interpretation of the statutory requirement of the identification of the provision of primary care services furnished by a physician, and the calculations of expenditures for the 3-year benchmark.<sup>12</sup>

This is a draconian solution to the need to standardize cost estimates across data sources, particularly when health economists have developed algorithms to match other incommensurate data sources with Medicare payment rates.<sup>13</sup> FQHCs now collect HCPCS codes for services<sup>14</sup> so this data matching function would need to be in place for only two years to accumulate the necessary baseline data. Indeed, CMS’s proposal to provide beneficiary identifiable claims data to ACOs acknowledges that HCPCS- included existent data may still be imperfect for ACO goal tracking<sup>15</sup> and will require, in essence, the creation of a “real time” data set for all ACO participants. We recommend CMS determine ways to fully incorporate FQHCs via, for example, the already existing methods to match otherwise incompatible data sets with the needs of the Medicare program.

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<sup>10</sup> 42 CFR Section 425.5(b).

<sup>11</sup> ACO Proposed Regulations at 44. FQHCs will collect HCPCS codes for services beginning in 2011 in preparation for the development of the FQHC Prospective Payment System. ACO Proposed Regulations at 45.

<sup>12</sup> ACO Proposed Regulations at 45.

<sup>13</sup> See generally Ciaran S. Phibbs et al., *Estimating the Costs of VA Ambulatory Care*, 60 Med. Care Res. Rev. 54S (2003).

<sup>14</sup> ACO Proposed Regulations at 45.

<sup>15</sup> ACO Proposed Regulations at 45.

**Provider Issues.** FQHCs make extensive use of primary care physician supervised team health care providers<sup>16</sup> in medically underserved areas.<sup>17</sup> The Medicare Claims Processing Manual acknowledges the value of this by spelling out that the FQHC encounter payment rate covers services provided by an FQHC physician, physician assistant, nurse practitioner, clinical nurse midwife, clinical social worker, and others.<sup>18</sup> Many FQHCs already embody, in short, a primary care model based on a multidisciplinary team approach.<sup>19</sup> CMS's earlier adoption of the encounter payment rate has encouraged this approach. It would be ironic to penalize with exclusion those further along the developmental timeline of more cost-effective integrated primary care for being just that.

**Unique Issues to RHCs.** RHCs represent a particularly compelling case for ACO formation inclusion. There are 274 Medicare Certified Rural Health Clinics in California, representing a little over seven percent of the national total.<sup>20</sup> There is currently little managed care penetration in California's rural areas.<sup>21</sup> If the promise of better integrated outpatient care is to be brought to California's rural Medicare beneficiaries, it will need to begin with RHCs. The exclusion of RHCs from those eligible to form an ACO will only serve to exclude rural providers and the populations they serve from forming efficiency-enhancing ACOs that might serve to counterbalance the inpatient service-favoring skew that has developed out of many rural preferential payment provisions.<sup>22</sup>

**Limited role for FQHCs and RHCs is not enough.** Although we acknowledge the intent to ameliorate this exclusion of FQHCs and RHCs by adding additional shared savings payments to both one-sided and two-sided ACO models that include a strong FQHC and/or RHC presence within the structure of the ACO,<sup>23</sup> we are not persuaded the proposed inclusion bonus programs are consistent with either the letter or the spirit of the Accountable Care Act. If FQHC participation is limited to participation only at the periphery of an ACO and if the FQHC patients may not be assigned lives for ACO benchmark and shared savings calculations, it is hard to see why any FQHC would be sought as an ACO participant. In addition, if "dually eligible" rural Medicare beneficiaries are particularly sought by CMS as ACO patient participants<sup>24</sup>, it is difficult to imagine how this goal may be reached absent FQHC and RHC inclusion in those entities eligible to form ACOs.

The Center for Medicare and Medicaid Innovation's Pioneer Accountable Care Organization Model Request for Application ("Pioneer ACO RFA") specifically "encourages applications from ACOs

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<sup>16</sup> See, e.g., Tim Bates and Susan Chapman, *Physician Assistant and Nurse Practitioner Staffing in California's Community Clinics: 2005-2008*, UCSF Center for the Health Professions (2010).

<sup>17</sup> Section 330 of the Public Health Service Act (42 U.S.C. 254b) defines federal grant funding opportunities for organizations to provide care to underserved populations.

<sup>18</sup> Department of Health and Human Services, Centers for Medicare and Medicaid services, Medicare Claims Processing Manual, Chapter 9, Section 20.1, CMS Pub. 100-2 (<https://www.cms.gov/manuals/downloads/clm104c09.pdf>).

<sup>19</sup> John Zweifel et al., *Creating an Effective and Efficient Publicly Sponsored Health Care Delivery System*, 22 J. HEALTH CARE POOR UNDERSERVED 311, 312 (2011).

<sup>20</sup> Kaiser, 2011

<sup>21</sup> Farra Bracht and Lisa Folberg, *HMOS and Rural California*, California Legislative Analyst's Office (2002); available at [http://www.lao.ca.gov/2002/hmos\\_rural\\_ca/8-02\\_hmos\\_rural\\_ca.html](http://www.lao.ca.gov/2002/hmos_rural_ca/8-02_hmos_rural_ca.html).

<sup>22</sup> Eileen Salinsky & Jessamy Taylor, Nat'l Health Policy Forum, *Exploring California's Rural Health System: From the Redwood Forests to the Baja Border* at 10 (2005).

<sup>23</sup> ACO Proposed Regulations at 45.

<sup>24</sup> ACO Proposed Regulations at 119.

led by FQHCs.”<sup>25</sup> The Pioneer ACO RFA outlines a program of modest scope, with CMS preparing to enter into participation agreements with no more than 30 organizations.<sup>26</sup> The requirement of 15,000 aligned beneficiaries may well rule out smaller safety net initiatives from participation in the Pioneer ACO RFA. In addition, interested organization letters of intent are due not later than June 10, 2011, or less than a month from the announcement of the Pioneer ACO RFA. We are concerned that safety net provider oriented ACOs may not be that quick out of the gate.

**Conclusion.** In short, FQHCs and RHCs should be included because they serve a significant portion of the Medicare population. The hurdles to participation outlined in the proposed regulations can be overcome by methods of data extrapolation, including some already used by CMS, and by the acceptance that the FQHC model of care delivery, far from being a liability, is an advantage in achieving the three-part aim of reduced costs, better care for individuals, and better health for populations.

## **II. ACO Operational Requirements That Disproportionately Burden Safety Net Providers**

In addition to the definitional and assignment based challenges to safety net ACO formation outlined in Part I of these comments, we are concerned that additional operational requirements found in the proposed regulations also present formidable barriers to safety net ACO formation. The key to safety net ACO formation and operation will surely be in making the ACO infrastructure no more burdensome or expensive than is absolutely necessary.

**Upfront Costs.** We are concerned that the upfront costs, particularly for the development of electronic medical records, may preclude safety net entity formation of ACOs. We are pleased to see the Advance Payment ACO proposal under consideration. We are particularly concerned that advance payment design be made available to safety net ACOs, even if this payment model is not adopted for ACOs outside the safety net. Given CMS’s plans to, for example, withhold 25 percent of shared savings payments to offset potential future losses, an Advance Payment Initiative could be crucial to the safety net’s participation. Moreover, the Initiative should be structured so as to, in effect, provide the “venture capital” safety net providers clearly need, but cannot otherwise access, to participate in the MSSP.

**Alternative Formation and Operation Models.** The ACO application itself will require submission of formation documents, quality assurance and clinical integration standards, ACO organization and management structure, evidence of a board-certified physician medical director, and documents relating to governing body composition.<sup>27</sup> We applaud the flexibility demonstrated by consideration of the possibility that substitute arrangements could be offered for any of these mandatory application materials.<sup>28</sup> In particular, we note that the requirements of a physician-led quality assurance and process improvement committee might be particularly onerous in rural areas where the acuteness of the physician shortages is such that many physicians in community clinics are already stretched quite

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<sup>25</sup> Department of Health and Human Services, Centers for Medicare & Medicaid Services, Pioneer Accountable Care Organization (ACO) Model Request for Application at 19 (2011) (<http://innovations.cms.gov/wp-content/uploads/2011/05/Pioneer-ACO-RFA.pdf>) [hereinafter Pioneer ACO RFA].

<sup>26</sup> Pioneer ACO RFA at 3.

<sup>27</sup> ACO Proposed Regulations at 65.

<sup>28</sup> *Id.* at 66.

thin with care delivery and administrative responsibilities. In particular, we propose that safety net providers be offered an alternative formation and operation option for the physician-led quality assurance and process improvement committee, substituting a physician-overseen quality assurance and process improvement committee.

**Impact of Unique Patient Population.** Smaller ACOs may, similarly, be disadvantaged by the proposed standards for promoting patient engagement. The safety net Medicare population is a more transient population than the general Medicare population.<sup>29</sup> Patient engagement, in this context, may be more challenging. The fostering of health literacy in a transient population may involve attempts to promote follow up appointments, for example.<sup>30</sup> The problem of churn in the safety net population will be a formidable one in light of the proposal to prohibit the ACO from developing any policies that would restrict a beneficiary's freedom to seek care from providers and suppliers outside of the ACO.<sup>31</sup> Alignment is more flexible than assignment,<sup>32</sup> but it is also harder to pursue continuity of care with non-assigned beneficiaries. In addition, the requirement that ACOs develop and implement individualized care plans for targeted patient populations<sup>33</sup> composed of high-risk individuals could be considerably more daunting for a higher risk general Medicare beneficiary population. We urge that safety net ACOs that disproportionately serve high-risk beneficiaries be rewarded for their patient population profile with risk adjustment based on diagnostic and not only demographic information.<sup>34</sup>

**Financial Rewards for Safety Net ACOs.** We urge you to consider providing financial rewards to safety net ACO Medicare beneficiaries who participate in safety net ACO governance. CMS has proposed that Medicare beneficiaries be directly involved in the leadership of ACOs, which we applaud, but this is a tall order that should be backed by rewards for safety net providers who achieve beneficiary representation. Further rewards should be available for safety net ACOs that successfully recruit dually eligible patients for seats on their governing boards. The presence of one beneficiary on a board should be a starting point, not a maximum, and CMS should emphatically support that mandate. Just as provider financial incentives must be aligned with better outcomes, safety net beneficiary participation should be aligned with fuller participation.<sup>35</sup>

**CMMI's Pioneer ACO Model.** As noted above, the Center for Medicare and Medicaid Innovation's Pioneer ACO Model RFA offers some relief from these disincentives to safety net ACO

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<sup>29</sup> Lewin ME, Baxter RJ. *America's Health Care Safety Net: Revisiting the 2000 IOM Report*. Health Aff (Millwood). 2007 Sep-Oct;26(5):1490-4.

<sup>30</sup> In this case the prospective treatment approach the safety net Medicare beneficiary would be contemplating is the decision to continue treatment.

<sup>31</sup> ACO Proposed Regulations at 81.

<sup>32</sup> *Id.* at 142.

<sup>33</sup> *Id.* at 93.

<sup>34</sup> Mark A. Hall, Risk Adjustment Under the Affordable Care Act: A Guide for Federal and State Regulators, The Commonwealth Fund 7 (2011), available at [http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2011/May/1501\\_Hall\\_risk\\_adjustment\\_ACA\\_guide\\_for\\_regulators\\_ib.pdf](http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2011/May/1501_Hall_risk_adjustment_ACA_guide_for_regulators_ib.pdf).

<sup>35</sup> Benjamin F. Springgate & Robert H. Brook, *Affordable Care Organizations and Community Empowerment*, 305 AM. J. MED. ASS'N 1800-1801 (2011).

participation. In particular, the expansion of eligible providers to include FQHCs<sup>36</sup> and the definition of an ACO professional's inclusion of practitioners who are physician assistants, nurse practitioners, or clinical nurse specialists<sup>37</sup> makes genuine room for safety net ACO participation. The allowance of non-physician primary care practitioners is consistent with the community clinic service model. The Pioneer ACO RFA outlines a program of modest scope, however, with CMS preparing to enter into participation agreements with no more than 30 organizations.<sup>38</sup> In addition, interested organization letters of intent are due not later than June 10, 2011, or less than a month from the announcement of the Pioneer ACO RFA.

The Pioneer Model RFA may also exacerbate one major barrier to safety net ACO participation. In particular, the requirement that there be a minimum of 15,000 aligned beneficiaries<sup>39</sup> discourages participation from smaller safety net providers. Alternatively, the faster track to ACO formation and participation may unwittingly promote provider concentration, not an unambiguous good in California's health care provider markets.

**Conclusion.** To facilitate successful ACO operation in the safety net, we recommend aggressive deployment of an Advance Payment Initiative, alternative operational standards, greater rewards for high-risk beneficiaries and beneficiary participation, and expansion of the promising Pioneer ACO Model.

### **III. ACO Formation and Operational Requirements That May Promote Provider Concentration**

The success of Medicare ACO initiatives, whether through the Medicare Shared Savings Program or the Pioneer ACO RFA will be judged, in part, by whether these programs involve provider groups of all types, not only large integrated group practices with affiliated hospitals. This measure of success is amplified by the acknowledgement that health care providers are more likely to integrate their care delivery for Medicare beneficiaries through ACOs if they can also use the ACOs for commercially insured patients.<sup>40</sup> “[P]roviders’ main purpose in forming ACOs may not be to achieve cost savings to be shared with Medicare but to strengthen their market power over purchasers in the private sector.”<sup>41</sup>

**Access to Specialists.** Safety net providers are typically not motivated by the drive to strengthen their market power over purchasers in the private sector. They will, however, run the risk of fallout from an increasingly concentrated market for specialists. If the safety net's ultimate ACO goal is a “publicly sponsored health care delivery system that combine[s] a primary care base built around community

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<sup>36</sup> Pioneer ACO RFA at 19.

<sup>37</sup> *Id.*

<sup>38</sup> *Id.* at 3.

<sup>39</sup> *Id.* at 30.

<sup>40</sup> Fed. Trade Comm'n & Dep't of Health and Human Serv., Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws (Oct. 5, 2010).

<sup>41</sup> Havighurst and Richmond, *The Provider Monopoly Problem in Health Care*, 89 OR. L. REV. 847, 872 (2011).

health centers with safety-net hospitals and the specialists that serve them,”<sup>42</sup> then specialists will need to play a major role in safety net ACO formation. The availability of specialists for safety net ACO participation may be diminished by the “growing frenzy of mergers involving hospitals, clinics and doctors’ groups eager to share costs and savings, and cash in on the incentives.”<sup>43</sup> We are in the midst of what has been labeled a “post-reform merger wave.”<sup>44</sup> But what is optimal for commercial insurance may be far from optimal for ACOs in the safety net. Nascent safety net ACOs will need access to a robust roster of specialists ready, willing, and able to participate to participate in a safety net ACO through either the Medicare Shared Savings Program or the Pioneer Accountable Care Organization RFA.

Great care has been given, in the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, to limit the safety zones of independent ACO participants (such as physician group practices) to a combined share of 30 percent or less of each common services in each PSA’s service area<sup>45</sup> but the calculation of the ACO’s share of services, as outline in the document’s Appendix, relies on the identification of Physician Service Areas based on retrospective ZIP code data. The PSA is a backward looking creation, in short. It tells us nothing about the willingness of important groups, like specialty physicians, to participate in Medicare going forward and whether those continuing to participate in Medicare are willing to serve a safety net population. A number of California specialty physicians, for example, accept Medicare only with the supplement of a substantial Medicare patient annual fee,<sup>46</sup> a requirement unlikely to make them accessible to the safety net patient population. CMS should counter this potential obstacle with rewards and/or incentives for specialists who participate in ACOs with safety net providers.

**Conclusion.** We acknowledge that a number of the problems with identifying providers willing to accept new Medicare safety net beneficiaries are beyond the scope of the Medicare ACO enterprise. But we are persuaded that nothing done to establish the program should worsen pre-existing problems with safety net Medicare provider participation. Therefore we recommend incentives and/or rewards for specialists who collaborate with safety net providers, and we urge the adoption of a rule that excludes all Medicare providers who require supplemental annual fees from the calculation of available specialists.

#### **IV. Provider Compensation and the Medicare ACO Proposed Rule**

**Fraud and Abuse Waiver Designs.** CMS has specifically solicited comment on the necessity for waivers for arrangements related to establishing the ACO when closely related to ACO formation,

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<sup>42</sup> John Zweifler et al., *Creating an Effective and Efficient Publicly Sponsored Health Care Delivery System*, 22 J. HEALTH CARE POOR UNDERSERVED 311, 316 (2011).

<sup>43</sup> Havighurst and Richmond, *supra* note 42 at 850 n.7, citing Robert Pear, *Consumer Risks Feared as Health Law Spurs Mergers*, N.Y. TIMES, Nov. 20, 2010, <http://www.nytimes.com/2010/11/21/health/policy/21health.html>.

<sup>44</sup> Tim Greaney, *Accountable Care Organizations and Antitrust: A New PSA Test* (April 1, 2011); available at <http://www.healthreformwatch.com/2011/04/01/a-new-psa-test/>.

<sup>45</sup> See Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program at 7.

<sup>46</sup> Christopher Weaver, *As Medicare Pay Shrinks, Some California Docs Hike Patient Fees* (March 16, 2010), [http://www.npr.org/blogs/health/2010/03/calif\\_heart\\_docs\\_hike\\_patient.html](http://www.npr.org/blogs/health/2010/03/calif_heart_docs_hike_patient.html)



compliance with MSSP regulations, or building IT or administrative capacity. As with any legal issue, one of the special challenges safety net ACOs will have to face in forming and then operating an ACO is capacity. Not only does the proposed regulations' requirement of an added compliance official<sup>47</sup> potentially drain safety net providers' coffers, but the addition of new regulations that require research and advice could also mean an increased financial burden for the safety net. The proposed fraud and abuse waiver designs are no exception. Therefore, CMS should consider whether safety net providers should be permitted to substitute another professional, such as a general counsel or head of administration, in the compliance official role.

There will be substantial legal work to do in the initial years of the program. For example, the phrase "necessary for and directly related to" will no doubt require interpretation by CMS, OIG and providers themselves before a working definition emerges. In a larger example, financial relationships other than shared savings payments, in order to be legal under the proposed waivers, must meet an existing exception to the Stark laws. Many such exceptions exist, such as bona fide employment relationships, personal service relationships and indirect compensation arrangements. However, obtaining solid legal advice about the new types of financial relationships that will form under the MSSP may require more legal resources than safety net providers have previously enlisted. Thus, there is a chance that, in spite of the proposed waiver designs, legal issues like fraud and abuse may prove to be obstacles or disincentives to safety net ACO formation. CMS should consider whether it can offer technical legal assistance, such as CMS or HHS-OGC attorneys, to assist safety net providers in navigating this facet of the MSSP.

**Additional Needed Waivers.** CMS is soliciting comments regarding additional waivers that would be necessary to carry out the provisions of the MSSP. Among the issues discussed is the use of existing exception and safe harbor for electronic health records (EHRs) arrangements. Although safety net providers are making progress with regard to EHRs, much work remains to be done. In California, for example, while almost half of the state's community clinics have implemented EHRs, one in ten have yet to even start the EHR process.<sup>48</sup> To ensure that anxiety about fraud and abuse laws does not impede the process, CMS and OIG should act affirmatively to guarantee the future of the present exception for EHRs.

In section II.B.9.d. of the discussion of the proposed rule, CMS notes that the provision of any free services between parties (such as ACO participants) in a position to generate Federal health care program referrals could trigger evaluation under fraud and abuse laws. "Processes to coordinate care" are statutorily mandated for the MSSP, and safety net providers may be more likely than others to share resources such as case managers and telehealth without charge. CMS should examine whether a specific waiver should be adopted to eliminate any disincentives for this type of activity where it serves the three-part aim of the MSSP.

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<sup>47</sup> 42 CFR Section 425.5(d)(10)(i)(A).

<sup>48</sup> Murchinson, et al., *For the Record: EHR Adoption in the Safety Net*, California HealthCare Foundation, February 2009; available at <http://www.chcf.org/~media/Files/PDF/E/PDF%20EHRAdoption.pdf>.

CMS has also solicited comment on distributions of shared savings or similar payments received from private payers. The fair competition guidelines issued by the FTC and DOJ are expressly aimed at “ACOs that participate in both the Medicare and commercial markets,”<sup>49</sup> and we believe CMS would do well to similarly integrate guidance to ACOs in other relevant arenas, notably Medicaid, in the proposed fraud & abuse waiver designs. This may help ensure that as many patients as possible reap the benefits of accountable care.

The MSSP proposed rule makes a limited number of additional references to fraud and abuse as justifications for certain proposed regulations. The proposed rule references, as one of the reasons retrospective beneficiary assignment is preferable, the potential for improper “inducements to overutilize services or to otherwise increase costs” for Medicare beneficiaries not assigned to an ACO. In other words, CMS was concerned that ACOs could, in a sense, “hide” expenses by associating them with beneficiaries for whom the ACO is not accountable via the MSSP.<sup>50</sup> This perfectly illustrates the continuing need for fraud and abuse laws. We agree that fraud and abuse laws should be, as CMS has proposed to do, waived in necessary circumstances, not repealed. And retrospective beneficiary assignment not only prevents the form of abuse described above, but also protects patient populations as a whole from the selective delivery of quality care.

**Conclusion.** Fraud and abuse laws play a vital role in the Medicare system, but waiving them for MSSP payments and in other circumstances, as CMS has proposed to do, is equally essential to the success of the MSSP. We recommend CMS consider relaxing a limited number of its governance regulations for the safety net, and that you offer technical assistance to help safety net providers navigate the new waivers. We also recommend CMS explore additional or more durable waivers for EHRs arrangements and processes to coordinate care. Finally, we recommend CMS consider offering guidance on the applicability of the MSSP fraud & abuse waivers to similar programs in Medicaid.

## V. Concerns Associated with Safety Net Patient Populations/Regions

**Allowances for Safety Net.** Health providers for the safety net know that safety net populations have special needs and circumstances that are sometimes overlooked. CMS has made some proposals for the MSSP that will benefit providers who treat patients in the safety net. For example, CMS has indicated outcome and patient experience measures “should be adjusted for risk or other appropriate patient population or provider characteristics.”<sup>51</sup> CMS has proposed to truncate beneficiary expenditures at the 99th percentile, and will not remove IME and DSH payments from the per capita costs included in the benchmark for an ACO. They are exempting small ACOs from the 2 percent net savings threshold and permitting them to share on first dollar savings under the one-sided model. We are pleased that that these provisions are present in the proposed regulations.

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<sup>49</sup> See Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program at 1.

<sup>50</sup> A similarly-aimed, but inverse, part of the proposed rule protects beneficiaries by prohibiting an ACO from avoiding at-risk patients. See, e.g., ACO Proposed Regulations at 21.

<sup>51</sup> ACO Proposed Regulations at 13.

**Rewards for Successful Responses to Diversity.** In addition, CMS has proposed to require ACOs to describe how they will partner with community stakeholders, and address diversity. Where diversity is concerned, safety net patient populations are like any other patient population in America—“only more so.” Therefore, safety net providers may need additional capacity to address issues such as language and compliance with provider instructions (issues which are, of course, interrelated). The challenge of serving particularly diverse Medicare beneficiary populations is endemic to the ACO program—found as well in the challenge of developing and using culturally appropriate shared decision making tools<sup>52</sup>, for example. Safety net ACOs that embrace these goals and perform to standard deserve additional compensation.

**Issues with Assignment and Participation.** The nature of providing for the health care of the safety net may also mean a bumpy road for ACO providers, particularly at the beginning. ACOs may need to bolster capacity mid-stream. Thus, CMS may need to reconsider its prohibition on adding ACO providers to an ACO during the 3-year agreement period. In addition, assigning beneficiaries solely to physicians designated as primary care providers may make it difficult (as CMS concedes) for ACOs to form in some geographic regions with such primary care shortages.

**Conclusion.** While the proposed regulations make some allowances based on the type of populations treated by an ACO, they should consider further rewards. CMS should also re-examine some provisions regarding how beneficiaries are assigned to ACOs, and when ACO providers can be added to an ACO, in order to best facilitate successful ACO formation in the safety net.

## **VI. The Medicare Shared Savings Program and Privacy**

The Proposed Rule discusses HIPAA and, to a lesser extent, the Privacy Act of 1974.<sup>53</sup> Generally, the Rule’s treatment of HIPAA is wise because it anticipates potential problems before they arise. For example, the Rule discusses at length that while ACO participants and ACO providers/suppliers are “covered entities” that must adhere to HIPAA, HIPAA permits disclosure of “the four identifiers” (name, DOB, sex and HIC) for “health care operations” purposes. CMS also proposes to proactively ensure that an appropriate Privacy Act system of records “routine use” is in place prior to making any disclosures, in order to avoid running afoul of the Privacy Act. The proposed rule even includes a data use agreement (DUA) that ACOs would have to accept to participate in the MSSP.

Without a doubt, this advance legwork is needed. Not only does the proposed rule specifically mention that some types of data use that could implicate HIPAA, but still other types of data mentioned in the proposed rule may present challenges in the future. For example, the proposed rule contemplates stepping up data collection on not only patient experience, but measures of caregiver experience.<sup>54</sup> We believe that as these measures expand, so too must CMS’s vigilance in clearing the logistical and legal way for achieving the three-part aim.

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<sup>52</sup>42 CFR Section 425.5(d)(15)(ii)(B)(3).

<sup>53</sup> See, e.g., ACO Proposed Regulations at 117.

<sup>54</sup> See, e.g., ACO Proposed Regulations at 195.

**The Need for More Education.** Research shows that health care providers are often anxious to a fault about complying with the provisions of HIPAA, and that safety net providers are no exception.<sup>55</sup> But more than anxiety, we have seen how HIPAA actually can prevent providers from acting--and enforcement agencies as well. CMS must act to ensure HIPAA does not paralyze participants in the MSSP. The DUA, and other safeguards, will ensure the protection of private information (as will the option for patients to opt out of data sharing).

**Conclusion.** We suggest CMS and CMMI should mount a substantial education campaign to inform MSSP participants about the requirements of HIPAA and the Privacy Act, with the specific goal of ensuring that needless anxiety about HIPAA does not interfere with work toward the three-part aim.

## VII. The Medicare Shared Savings Program and State Law

**State Regulation of Risk Bearing Entities.** CMS notes they do not intend for the MSSP to render States responsible for bearing any costs resulting from its operation. But they acknowledge that “some States may regulate risk bearing entities.”<sup>56</sup>

Indeed, the California Department of Managed Health Care (DMHC) announced in January their intention to regulate ACOs, and elaborated at a recent meeting.<sup>57</sup> The Department’s jurisdiction is triggered when any person undertakes to arrange for the provision of health care services to subscribers or enrollees, or to pay for or to reimburse any part of the cost for those services; and is compensated based on a prepaid or periodic charge paid by or on behalf of the subscribers or enrollees. At the moment, the California DMHC has taken the position that ACOs under the MSSP are not subject to their licensure requirements due to the fact providers are still paid on an FFS basis.<sup>58</sup> The California DMHC has not yet taken a position on the partially capitated ACOs outlined in the Pioneer ACO RFA. Yet in the state’s health care system as a whole, ACOs are on notice that California may regulate them.

**State Law and ACO Governance.** Among other additional state law impacts, CMS notes in its proposed rule that state law may be implicated by the regulations’ requirement that ACOs have a Medicare beneficiary on their governing boards. CMS also seeks comment on the degree to which state insurance laws may be implicated by the regulations. The greater the legal barriers to participation in the MSSP, the less likely health providers are to participate—especially safety net providers lacking the capacity or confidence to enter new legal arenas.

**Conclusion.** CMS should begin discussions with state policymakers and other stakeholders now to ensure that the MSSP can go forward and that state laws and regulations do not serve as additional disincentives to MSSP participation by safety net providers.

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<sup>55</sup> See, e.g., *The Impact of Fear of HIPAA Violation on Patient Care*.

Touchet BK, Drummond SR, Yates WR. *PSYCHIATR SERV*. 2004 May;55(5):575-6.

<sup>56</sup> ACO Proposed Regulations at 310.

<sup>57</sup> California Department of Managed Health Care, *Accountable Care Organizations Oversight Impelementation* (May 19, 2011). Available at <http://www.dmhc.ca.gov/library/reports/news/fssbacooi.pdf>.

<sup>58</sup> *Id.*

## VIII. Conclusion


The Medicare Shared Savings Program is a major step on a promising path toward improvement of health outcomes for all Medicare beneficiaries. Safety net patients, far from being at the periphery of health care reform, need its benefits the most--and also offer providers the chance to create savings via well-coordinated care by ACOs.

We respectfully request the Centers for Medicare & Medicaid Services of the Department of Health and Human Services, the Center for Medicare & Medicaid Innovation of the Department of Health and Human Services, the Federal Trade Commission, the United States Department of Justice, and the Office of Inspector General of the United States adopt final regulations for the Medicare Shared Savings Program consistent with our recommendations.

Sincerely,



Ann Marie Marciarille  
Senior Research Fellow, Berkeley Center on Health  
Economic & Family Security



Matthew A. Chayt  
Legal Fellow, Berkeley Center on Health, Economic  
& Family Security