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June 2, 2011

Submitted electronically to <http://www.regulations.gov>

Donald Berwick, M.D., Administrator
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: CMS-1345-P, Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations

Dear Dr. Berwick:

On behalf of Billings Clinic, we are writing to you today regarding Section 3022 of the Affordable Care Act (ACA) notice of proposed rule-making (NPRM) for the Medicare Shared Savings Program/Accountable Care Organizations (ACOs).

We understand and appreciate the complexity of the task which the Centers for Medicare and Medicaid Services (CMS), along with the Federal Trade Commission, the Department of Justice, and the Internal Revenue Service, faced in drafting the proposed rule and the related guidance. We have participated in the Physician Group Practice (PGP) demonstration program over the past five years and are strong supporters of the Accountable Care Organization (ACO) concept as envisioned in the ACA. Further, we have been committed to a partnership with CMS to provide care coordination and the sharing of information across the continuum of care directed toward improving health outcomes, lowering costs, and increasing quality of care.

As presently drafted, the proposed rule is overly prescriptive, operationally burdensome, and does not provide sufficient incentives for health care providers to voluntarily move away from traditional fee-for-service (FFS) reimbursement. Shared savings payments are a critical part of this transformation and are necessary to make the technology and other infrastructure investments needed to transform care delivery.

Billings Clinic would like to recommend that CMS approach the final rule with the intent of creating the conditions to encourage engagement of patients and providers in an effort to generate real movement toward improving care, improving health, and reducing cost. By developing a simplified regulatory framework based on some key minimum specifications, CMS will create the incentive for providers to integrate, invest in technology, and care coordination. Research demonstrates that these attributes result in better outcomes at lower cost.

The simple rules we suggest are patient and provider engagement through prospective attribution, shared savings percentages that increase provider reward, a reasonable number of quality measures phased in over multiple years, a threshold for savings of 2% for all ACO participants with first dollar shared savings once 2% is achieved, more flexibility in the area of improvement of severity scores, the use of targets based on national benchmarks with some adjustments for certain payment policies, more timely data and information feedback, and development of collaborative shared learning opportunities for ACO participants.

Additional background and rationale for each of these suggestions follows.

Patient Engagement

A critical principle in health reform is the recognition that health care is a *shared responsibility*. Employers, individuals, and government all have a role to play—and a contribution to make—to the system. In this new model, ACOs should create informed and involved consumers who are encouraged to be an active participant in their health and health care.

CMS proposed to assign Medicare beneficiaries to an ACO retrospectively, but provide ACOs with preliminary assignment information at the start of the performance period and annually thereafter. The agency further proposes to assign beneficiaries to an ACO if they received a plurality of their primary care services (allowed charges, not units of service) from a primary care physician (internal medicine, family practice, general practice, geriatric medicine) within that ACO.

Retrospective attribution places limits on the ACOs ability to bend the cost curve. It impedes optimal patient engagement, timely program planning and course correction, and compounds underlying issues of claims lag and financial settlement. Attribution or assignment is a two-way street. It is just as important for the patient to know who they are assigned to as the provider to create the optimal relationship for health promotion and care management. It is this prospective view that creates the opportunity to change the sick care system into a true health care system.

CMS has, in the proposed ACO rule, recognized the need for some prospectively provided information, pledging to give the names, dates of birth, gender, and Medicare numbers of those assigned to the ACO at the start of each performance year. This is coupled with provision of quarterly reports of aggregated, de-identified data from Parts A, B, and D claims for patients who do not opt-out of that data sharing.

These efforts at data sharing, if actually implemented, would go a long way to improving the ability of the ACO to develop programs to coordinate and improve care. During the PGP demonstration, CMS shared that Medicare beneficiaries have an average two-year “stayer” rate of 80%, resulting in a significant change each year in beneficiary assignment. We believe that most Medicare Advantage plans could deal effectively with that kind of turnover. Retrospective assignment simply ignores the power of patient engagement that occurs with enrollment/election.

Though the proposed rule claims to be patient-centric by championing “choice,” it actually ignores all of the evidence that patients need to be accountable for improving/maintaining their health. This begins with an active decision to partner with their providers in care.

CMS also proposes to make available standardized written information to the Medicare FFS beneficiaries whom they serve, notifying them of both the providers' participation in the program and the potential for CMS to share beneficiary identifiable data with ACOs when a beneficiary receives services from a physician on whom assignment to the ACO is based. What CMS has proposed is perhaps not best for either the beneficiary or the providers. If beneficiaries can opt-out of the data sharing but not the program, providers will not have sufficient information to properly care for and manage the beneficiaries. Beneficiaries should be given the opportunity to fully withdraw from the program without having to seek care from another provider. This opt-out would prevent data from being shared with the ACO, but clearly allows beneficiaries to stay with their existing physician. We are concerned that this form of an opt-out program could disrupt the established relationships with many primary care providers, as the beneficiaries may very well be skeptical of the program at first and will want to wait to determine if they would like to participate. CMS should structure an opt-out option that prevents both data sharing and attribution of that beneficiary to an ACO while allowing them to continue seeking care from their usual providers.

CMS further proposes that all ACO marketing materials and activities must be approved by CMS prior to use. The regulation text defines "marketing materials and activities" as including, but not being limited to, "general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, data sharing opt-out letters, mailings, or other activities conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/ suppliers participating in the ACO, or by other individuals on behalf of the ACO or its participating providers and suppliers when used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the Shared Savings Program." Further, before any changes can be made to any approved materials, the revised materials would first have to be approved by CMS. The proposed rule warns that an ACO that fails to adhere to these requirements may be placed under a corrective action plan or terminated at CMS' discretion.

We question the value of forcing ACOs and CMS to invest significant resources in an approval process when the likelihood of harm is negligible. The proposal is far more prescriptive than necessary and again attempts to regulate what should be considered business operations. We would favor stating what behaviors are inappropriate, then conduct reviews as appropriate to ensure compliance, and otherwise allow the use of the majority of communications without approval, rather than listing a limited scope of appropriate communications.

Shared Savings

ACOs that meet the quality performance standards established by the Secretary and that achieve savings compared to a benchmark of expected average per capita Medicare FFS expenditures will share in a portion of the Medicare savings.

We strongly favor a simplified shared savings design. Random variation can work in both directions and setting higher thresholds may protect CMS from random variation, but does not protect or recognize random variation that might affect providers negatively. We would strongly favor using a 2% threshold for all ACO populations regardless of size. Once a 2% threshold is met, savings in that first 2% should also occur. We believe this adequately protects CMS from incurring increased spending. In addition, especially given the increased up front investment costs required of ACOs, we strongly recommend increasing the percentage of shared savings going to ACOs to 75% or 80%.

There is a downside risk during the initial three-year term, unlike the recently concluded PGP demonstration project. Such downside risk is compounded by significant investment cost on the part of the ACO. This will discourage provider participation. CMS should include a payment track that relies solely on a shared saving model with no down-side risk for the first three-year contract.

The law directs CMS to establish benchmarks that are updated each year by the absolute growth in the national adjusted per capita spending across Medicare Parts A and B for the associated beneficiaries. CMS needs to strike a delicate balance in crafting the benchmark and expenditure calculations. CMS should adjust the spending calculations for wage differences and add-on payments such as disproportionate share hospital (DSH), indirect medical education (IME), and direct medical education (GME). Standardizing Medicare FFS payments for these policy and market adjustments will more accurately reflect resource utilization, a metric that ACO controls, when calculating annual per capita expenditures. The exclusion of wage differences, such as the Frontier States policy adjustment, is of critical importance to Billings Clinic.

Changes in the case mix of assigned patients stemming from changes in the health status of assigned patients or changes in the ACOs organizational structure could affect expenditures. Risk adjustment is of paramount importance for the ACO program, as the enhanced benefits will inherently draw a higher acuity patient population. CMS concluded that ACOs hierarchical condition categories (HCC) risk scores are likely to increase significantly due to more complete coding, rather than patient acuity. Therefore, CMS proposes to calculate a single benchmark risk score for each ACO. The same risk score will be applied throughout the agreement period. This will unduly penalize ACOs who treat a high-risk population with severe conditions that will naturally progress in acuity even under the best possible care. In addition, for some ACOs without coding experience, baseline severity scores may not accurately capture patient population severity. Also the acuity of the patient population may well increase over time and coding should be allowed to reflect that change. ACOs will be interested in caring for the sickest and hardest to treat patients that are most in need of care coordination. Limits placed on accounting for beneficiary acuity level that is documented and appropriate will dilute true savings realized by the ACO, and is a disincentive for management of patients with complex care needs. CMS should devise a system that allows for appropriate risk growth during the performance period.

Quality Measures

CMS proposes to use 65 performance measures in year one of the ACO program, with ACOs required to report full and accurate data for those measures, but not meet any specific performance target. The magnitude of the proposed measures in the first year of the program is concerning. While we appreciate that CMS has largely used measures with standard definitions that have been tested and are in wide use (including other Medicare programs), the number of measures required is far greater than the initial Physician Group Practice demonstration and Hospital Inpatient Quality Reporting program, both of which have been in operation for more than five years. CMS should reduce the number of performance measures in the initial measure set.

We would recommend adopting a phased approach to performance metrics. A phased approach to performance measurement: 1) serves to encourage and promote maximum participation by eliminating data collection barriers, 2) allows institutions wishing to form an ACO to start now without waiting for the perfect measurement framework, and 3) leaves the door open for continuous refinement and innovation in performance assessment. The excellent results produced by the PGP demonstration organizations are evidence of the benefits of a careful expansion of quality measures.

Lastly, we would recommend the development of learning collaboratives so that ACO participants can learn from one another and better diffuse best practices.

Antitrust Concerns

Given our vast rural market area and the tertiary hospital and subspecialty medical services that Billings Clinic offers, we have been particularly interested in how the guidance would facilitate ACO development with rural health care organizations. In our market, critical access hospitals often employ their physicians or non-physician providers, operate post-acute care services, and function as a single vertically integrated organization. We are concerned that the mandatory review threshold of 50% is too low. Should we develop an ACO that includes regional critical access hospitals and their medical staffs, it is highly likely that the PSA share of combined common services would exceed 50% in both Medicare and non-Medicare services. In addition, the rural exception in the antitrust safety zone for ACOs is too narrow and does not reflect the realities of a frontier marketplace.

In closing, we appreciate the opportunity to submit these comments. We look forward to working with you and other federal policymakers to offer suggestions for revising the current proposed rule and achieving our shared goal of improving quality and lowering costs for Medicare patients. Should you have any specific questions, or wish to discuss our comments further, please contact Kristianne B. Wilson, Executive Director, Health Policy, at kristianne@billingsclinic.org or 406-255-8452 or me at nwolter@billingsclinic.org or 406-238-2609.

Sincerely,



Nicholas Wolter, M.D.
Chief Executive Office

Copy: Senator Max Baucus, United States Senate
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