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June 2, 2011

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

Re: Medicare Shared Savings Program: Accountable Care Organizations (CMS-1345-P)

Dear Dr. Berwick:

The Marshfield Clinic respectfully submits these comments in connection with Section 3022 of the Affordable Care Act's notice of proposed rule-making (NPRM) for the Medicare Shared Savings Program/Accountable Care Organizations (ACOs).

As you well know, Marshfield Clinic has had the honor of participating in the CMS Physician Group Practice Demonstration since its inception. Given the complex nature and multiple factors involved in large scale change initiatives during a period of fee for service reimbursement, coupled with the need to test new methodologies with CMS, the level of success in the PGP demonstration project can be viewed positively as the groups needed to meet their current business needs and move to an uncertain reimbursement stream with no upfront money for infrastructure change. At Marshfield Clinic, we believe our patients have benefited greatly from our participation in the project, while we have learned a great deal to help all of our patients (not just our Medicare patients) from our interactions with CMS directors and consultants, as well as peer PGP sites. We believe that the Accountable Care Organization concept holds great promise as a platform for enabling the integration of high quality and efficient services necessary for improving the health and wellbeing of the nation to work to achieve the "three aims" as proposed by the CMS.

We commend CMS for the profound effort and integrity your efforts. We have great expectations that the final rulemaking will be viewed as a milestone in the evolution of modern clinical practice.

Marshfield Clinic (the "Clinic") is a large private group medical practice in Wisconsin. It is one of only a few large independent not-for-profit, tax-exempt medical clinics in the United States. The Clinic is engaged in providing quality health care, health care education, and medical research. The Clinic owns a small critical access hospital and a small rural hospital and operates outpatient clinical, educational, and research facilities with its main clinical facilities and administrative offices located in Marshfield, Wisconsin. The Clinic currently employs more than 779 physicians and 6500 additional staff. The Clinic has 55 regional centers in addition to the Marshfield location and operates in 37 Wisconsin communities throughout Central, Western, and Northern Wisconsin, which is a predominantly rural area. Marshfield Clinic has developed and acquired sophisticated tools, technology, and other resources that complement and support the population health management mission and strategy of the Clinic. These include an electronic medical record, a data warehouse, an immunization registry, and an epidemiological database that enable enhanced

definitions of disease states, diagnoses or conditions, and cost analysis of CPT level interventions. Marshfield Clinic is a partner in Family Health Center, a federally qualified healthcare center, and has been instrumental in advancing innovative methods to assist this population, such as dental care options to improve medical care. All of Marshfield Clinic's regional centers are linked by common information systems. With this infrastructure, the Clinic is presently publicly reporting clinical outcomes, and providing physicians and staff quality improvement tools to analyze their clinical and business processes, eliminate waste and unnecessary redundancies, and improve consistency while simultaneously reducing unnecessary costs. Marshfield Clinic is unique in that it has developed its own electronic health records and ancillary reporting systems over the last thirty years. The system, called CattailsMD, was the first internally-developed system to gain CCHIT certification.

We humbly submit that we have long thought of the Clinic as an early adopter and have adapted our proprietary system to facilitate a clinical practice of evidence based medicine. We believe that the objective of meaningful use of health information technology articulated by CMS and ONCHIT leads down a path of continual innovation and improvement that is at the core of the ACO objective. We are currently working to obtain patient centered medical home recognition through the National Committee of Quality Assurance (NCQA) program and anxiously await the outcome of that effort. We believe that the adoption and meaningful use of electronic health records (EHR), patient centered medical home and coordination of care efforts are essential to the successful implementation of CMS's objectives regarding Accountable Care Organizations and other incremental efforts to improve the health and well being of the nation's population. An interoperable superstructure or data warehouse is also necessary to assure the continuity of patient care in various locations.

We understand and appreciate the complexity of the task which the Centers for Medicare and Medicaid Services ("CMS"), along with the Federal Trade Commission ("FTC"), the Department of Justice ("DOJ"), and the Internal Revenue Service (IRS) faced in drafting the proposed rule and the related guidance. As leaders in providing integrated care, we are strong supporters of the Accountable Care Organization ("ACO") concept as envisioned in the Patient Protection and Affordable Care Act ("PPACA"). Further, we are committed to a partnership with CMS to provide care coordination involving collaboration among providers and suppliers and the sharing of information across the continuum of care directed toward the three-part aim: (1) better care for individuals; (2) better health for populations; and (3) lower growth in expenditures.

We support the concept of ACOs as envisioned in the Affordable Care Act because of the need to ensure that patients, over time, receive the best and most efficient care possible to truly deliver value to all stakeholders. To do so, requires more coordination and collaboration among providers and suppliers than is the case in much of our healthcare system today. We encourage CMS to become more proactive about identifying the many currently uncompensated prevention services which are necessary to promote healthy populations and prevent the progression of disease. Reimbursement for strategies that prevent hospitalizations and re-admissions must be improved. Payment for counseling for smoking cessation, substance abuse, diet and obesity, as well as disease management activities such as nurse helplines would help bridge the gap as ACOs or potential ACOs wait for performance payments.

We believe that it will be important to develop alternative payment systems that properly reflect the emerging realities of delivering health care in the US. Some of the emerging ideas, including the concepts for Accountable Care Organizations and Patient-Centered Medical Homes will require fundamentally different payment arrangements and therefore fundamentally different data

collection systems to ensure equity in payments for Medicare services and control over global Medicare expenditures. In our view, it is not too early to begin the process of identifying payment options and the data systems that are available and/or needed to support such options.

However, as presently drafted, the proposed rule insufficiently advances our shared goals of cost reduction and improved patient outcomes because of an excessive focus on shifting risk to providers. In the spirit of constructive suggestions, we believe that health systems will be much more likely to participate in the Medicare ACO program if CMS focuses on changes to the following aspects of the policy proposals:

Limits placed on accounting for beneficiary acuity levels that are documented and appropriate will dilute true savings realized by the ACO and will be a disincentive for management of patients with complex care needs and may have unintended consequences for beneficiaries. We support CMS' proposal to employ a methodology that incorporates diagnostic information, specifically the CMS-HCC prospective risk adjustment model that has been used under the MA program. We view the concept of coding intensely to be synonymous with coding accurately. With EMRs and the advent of ICD-10 coding, coding accuracy by providers will improve, especially among ambulatory providers who previously followed CMS guidance to limit coding to the top three diagnoses. We encourage CMS to begin programs to educate physicians and other providers about the importance of coding accuracy. Appropriate diagnostic coding helps to appropriately identify healthcare needs and leads to appropriate treatment. Knowing that a patient has a previous myocardial infarction serves as a reminder of necessary pharmacologic (antiplatelet agents, beta blockers, statins) and lifestyle modifications (diet, exercise, tobacco cessation) that might be otherwise not considered if the diagnosis is not clearly reaffirmed with acknowledgment of the increased risk and utilization of resources necessary for a patient in this situation. Using diagnostic information will likely lead to some degree of increased identification of higher-cost conditions, but some degree of increased diagnostic coding is desirable in order to correct for inaccurate or undercoding. If necessary CMS could institute a chart audit program to determine coding veracity. We respect CMS' need to hold spending to a budget neutral amount, but CMS should not be in the position of perpetuating disparities in care for patients, disparities in reimbursements for providers, or shortcomings in the integrity of CMS' knowledge of the presence of disease in the population based on previous coding practices which will almost certainly undergo significant change with the implementation of ICD-10 in 2013.

Number and calculation of quality metrics: For 2012, CMS proposes to use a number of quality measures to establish the quality performance standard ACOs must meet in order to share in savings, provided they also meet the program's cost savings requirement. These 65 measures span five quality domains : Patient Experience of Care, Care Coordination, Patient Safety, Preventive Health, and At-Risk Population/Frail Elderly Health. We believe that quality metrics are important for patients, CMS and providers. Instituting 65 measures in year 1 is a substantial practical constraint. We recommend that CMS phase in quality measures over time. CMS should only require Medicare ACOs to report on quality measures that improve population health outcomes and efficiency. We encourage CMS to focus on a limited number of high-impact quality measures during the first years of the Shared Savings Program. Many of the 65 proposed measures are not currently collected by all providers. According to a recent Health Affairs article, only 11 of the 65 measures can be met with claims data, while 54 require potentially expensive data collection from medical records or surveys. Claims data was clearly never intended for use in quality improvement and has many shortcomings in this arena. Ultimately, CMS should select measures that not only are clearly linked to improving quality outcomes, but also do not require providers to create and/or invest in new data collection and monitoring systems that are unrelated

to those already in place, such as ARRA Stage 1 meaningful use requirements. Data collection on quality metrics for ACOs should be harmonized with meaningful use requirements to assure that ACO resources expended to achieve compliance are not wasted on redundant or conflicting measures of quality and meaningful use. Collection of such a large number of measures will not allow for the timely development of education, appropriate tools and feedback to truly allow providers to improve care delivered to their patients.

Potential costs of ACO program participation. The proposed rule estimates that the average cost of starting an ACO will be \$1,755,251 with the expectation that total start up costs may vary by a factor of 2. A recent study by the American Hospital Association estimated start-up costs of as considerably higher: \$11.6 – \$26.1 million per facility. The dilemma for an organization contemplating a transition to an alternative reimbursement strategy resides in the allocation of fee-for-service revenue to activities that are desirable but currently uncompensated. Care must be coordinated; systems put in place to support transitional care, EMRs must be programmed; disease management strategies must be established and disseminated among caregivers; patients must be educated and supported in healthy lifestyles. We are concerned that CMS has no appreciation for the difficulties and challenges of creating a new type of healthcare entity that agrees to be held accountable for improving the health and experience of care for individuals and improving the health of populations while reducing the rate of growth in healthcare spending. We recommend that CMS consider alternative payment arrangements in localities where per capita health expenditures are at or below the national average. On many occasions now we have provided comments and testimony advising CMS, HHS, Congress and the White House with information and data showing that the Medicare program is only reimbursing Marshfield Clinic for about 50% of its Medicare Allowable Costs in providing services to Medicare beneficiaries even taking into consideration the bonus payments the Clinic has received for its performance in the PGP demonstration. This inequity must be addressed soon.

Retrospective attribution places limits on the ACO's 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. During the CMS PGP demonstration project, Marshfield Clinic made a conscious decision to treat all patients (Medicare, Medicaid, commercially insured and uninsured) with the same programs and initiatives. We believe we could have been even more successful with prospective assignment of patients to allow programs to focus on those patients who would benefit the most in a proactive fashion. We are uncertain about accepting downside risk for patients that we are not aware of. We would be more comfortable with downside risk for patients that we are prospectively aware of. Consequently we recommend that CMS consider holding potential ACOs harmless for downside risk for patients that cannot be prospectively identified.

The logistics associated with Medicare beneficiaries' opt-out of the ACO program are simply not practical. We believe this would lead to beneficiary and physician confusion on the terms of engagement. We ask: how can any provider practically agree to this and yet still manage care? HIPAA allows providers and payors to share PHI without patient/subscriber consent for purposes of treatment, payment, and healthcare operations. Has CMS intended to propose data/PHI sharing rules more restrictive than that specified by HIPAA? In addition the provision allowing patients to opt out of sharing claims data within an accountable care organization runs counter to the desired goal of coordination of care by sharing information between entities providing care to a patient.

Changes in reimbursement for the future. The options for changes in reimbursement in the future may include: fee for service plus shared savings, episode of care payments, partial to full capitation payment methods. In order for those methods to be effective accurate risk adjustment methodologies must be utilized to avoid adverse selection of patient populations. Conversely, accurate risk adjustment would also encourage organizations to build the disease management infrastructure to address the needs of the most complex patients with multiple chronic diseases. The care of chronic illness currently consumes approximately 75% of total healthcare expenditures annually. We encourage CMS to be proactive and aggressive about addressing the needs of these patients in both the Medicare and Medicaid populations.

Timeliness of feedback – Marshfield Clinic has been pleased to be able to work with the CMS during the PGP demonstration program. Having data regarding claims and quality measures in near real time format would be very helpful for assigned beneficiaries to which patients could benefit the most from intervention. Additionally, timeliness of information for feedback allows better assessment of interventions to determine which interventions are truly of value to patients from both quality and cost perspectives. Additionally, from a perspective of financial viability and sustainability, shared savings opportunities need to occur in a more rapid fashion than occurred in the PGP demonstration project where shared savings were available on average eighteen months after the end of a performance year.

These broad categories reflect our most serious concerns related to our support for the ACO program as an avenue to promote value in health care delivery. As a whole we are delighted with the progress that CMS has made in the initial proposal. We are confident that CMS shares our determination to improve care for individuals and the health of populations at lower costs. We strongly urge you not to yield to politically motivated pressure to pull down the rule and start over as some have suggested.

Marshfield Clinic's mission is to serve patients through accessible, high quality health care, research and education. Our primary health policy concerns support this mission so that all state and federal government elected and appointed officials, insurers, employers, providers and patients understand and engage us as a health care system on the basis of our commitment to the health and well being of the communities we serve.

We look forward to working with you and other federal policymakers on this matter for improving the current proposed rules and achieving our shared goals for patients and providers alike. I can be reached at (715) 387-5763; please do not hesitate to contact me, Karl Ulrich, MD, our President/CEO at (715) 387-5253, or Theodore A. Praxel MD, MMM Medical Director, Quality Improvement & Care Management at (715) 389-3188, if there is any way that we can assist you.

Sincerely,



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