SISTERS OF MERCY
HEALTH SYSTEM

May 31, 2011

Donald M. Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS – 1345 – P, Medicare Shared Savings Program: Accountable Care Organizations

Dear Dr. Berwick:

Mercy Health ("Mercy") is pleased to provide the following comments in response to the above referenced proposed rule published by the Centers for Medicare and Medicaid Services ("CMS") in the Federal Register on April 7, 2011. We have also included as attachments for your information our comments to the related Notice Regarding Waiver Designs published by CMS and the Office of Inspector General ("OIG"), IRS Notice 2011-20 published by the Internal Revenue Service ("IRS") and the FTC/DOJ Proposed Statements of Policy and Safety Zone published jointly by the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ").

Mercy is a Catholic, not-for-profit, health ministry which, through its affiliated organizations, operates hospitals, physician practices, outpatient clinics and related health and human services in a seven-state area including Arkansas, Kansas, Louisiana, Mississippi, Missouri, Oklahoma and Texas. Mercy's services and facilities include 28 owned and managed hospitals with more than 4,600 beds, three heart hospitals, a rehabilitation hospital, more than 200 outpatient care facilities, physician practices, home health programs, skilled nursing facilities and long-term care facilities. The communities served are both urban and rural. Services are provided by approximately 36,000 co-workers and 4,500 physicians, of which approximately 1,500 are employed in multi-specialty Mercy clinics. Nearly 2.7 million lives are touched directly by Mercy every year. Mercy is completing the implementation of the EPIC electronic health record system across the ministry and expects to qualify for the HITECH "meaningful use" incentive payments. Our affiliated entity, Mercy St. John's Clinic in Springfield, Missouri is one of ten physician group practice organizations nationwide currently participating in the Physicians Group Practice Demonstration Project ("PGP Project") and has qualified for shared savings incentives under that project.

14528 S. OUTER FORTY ▪ SUITE 100 ▪ CHESTERFIELD, MO 63017
314-579-6100 ph.

Mercy supports the concept of ACOs as envisioned in the Patient Protection and Affordable Care Act. The three-part aim of the ACO Program, better care for individuals, better health for populations, and lower growth in expenditures, is consistent with Mercy's mission and strategic direction. Mercy has long pursued the goal of delivering the best and most efficient care possible through better coordination and collaboration among care givers within Mercy. We believe our model of integrating our physicians and advanced practitioners more closely with Mercy, along with our related quality, safety, service and care management strategies, are helping us deliver the right care at the right time, all the time. Through our Healthification programs and support of the Health Teachers curriculum, we are also promoting better health for our communities, and our care management co-workers are dedicated to eliminating waste and inefficiencies in delivering appropriate care while not withholding needed care.

Although we appreciate the hard work of CMS to move ACOs to reality, we have significant concerns with the current proposed regulations on ACOs as well as with the related waivers and Policy Statements. As a participant in the PGP Project, we know firsthand the challenges and costs of building the necessary infrastructure, collecting, reporting and acting on the necessary clinical data and changing our clinical culture accordingly. We are particularly concerned with the numerous prescriptive requirements that seem to have little to do with outcomes but create significant administrative burdens on prospective ACO participants that are even greater than those in the PGP Project. Further, we have concluded that the new requirement that an ACO undertake the risk of sharing in the losses will likely be a significant barrier to many of Mercy's provider communities that did not participate in the PGP Project and do not yet have the information and care management structures in place to take on such risk. The comments and recommendations below are intended in good faith to improve the proposed regulations to encourage greater participation and engagement with this innovative concept.

I. <u>Shared Savings</u>

We believe the two risk models proposed by CMS, one of which includes two-sided risk in year 3 only and the other of which includes two-sided risk in all 3 years, will discourage many organizations from pursuing ACO status. This is especially the case for those communities that have not yet built the infrastructure needed to manage this risk. Therefore, we propose the addition of a third option, similar to the PGP Project, that does not include a downside risk for the ACO in any year during the term of the ACO Agreement with a maximum sharing cap for each of the three years at 5% of shared savings. We also recommend that the shared savings cap in Option 2 be increased to 7.5%, 10.0% and 15.0% to further incentivize the formation of ACOs willing to pursue this option thereby potentially increasing benefits to Medicare beneficiaries and to the Medicare Program.

Although not the subject of this comment letter, we appreciate the greater

incentives and flexibility included by CMS in the recently proposed description of Pioneer ACOs. Based on our participation in the PGP Project, we believe the costs of forming and operating a successful ACO are significant and should be recognized through greater sharing of the savings achieved.

Consistent with our PGP Project experience, we also believe CMS should further decrease the minimum savings/loss thresholds below 2% as the population of Medicare beneficiaries served increases since the randomness of the data decreases as the cohort size increases. We note that the proposal with respect to Pioneer ACOs suggests a 1% threshold which we appreciate but also believe should be even lower for larger populations of Medicare beneficiaries. We recommend that CMS incorporate a sliding scale that decreases as the size of the cohort increases.

We believe a withhold of 25% of Shared Savings each year as a reserve against possible future losses creates an unnecessary disincentive to ACO participation and should only apply in limited cases. Instead we suggest that CMS include in the ACO application process alternative methods to satisfy itself that the ACO will pay its share of losses when and if they should occur. Such alternatives could include letters of credit, guarantees by investment grade entities or maintenance of sufficient financial reserves.

II. Benchmark and Adjustments

Mercy supports the use of a national benchmark but recognizes it may be necessary to transition to a national benchmark by using a blended rate over three years. We suggest a 50-50% blended rate in year 1; 75-25% blended rate in year 2 and 100% national rate in year 3.

Because of beneficiary movement and the changing severity of disease, we believe there must be an annual severity of disease adjustment to the benchmark. To assist CMS in confirming the accuracy and fairness of such adjustment, we suggest a cap of 10% on any annual increase based on coding severity unless the ACO can provide a satisfactory sampling of assigned beneficiaries audited to support the proper coding and higher risk adjustments.

We recommend that CMS create a mechanism for adjusting the benchmark and actual results in its calculations of shared losses or shared savings to eliminate the impact of new payment programs, like various rural health payments or bonuses, which do not reflect the delivery of more costly care.

We also have reservations about the inclusion of Disproportionate Share Hospital (“DSH”) and Indirect Medical Education (“IME”) payments in the benchmark and other calculations. Their inclusion potentially discourages use of those institutions that qualify for such payments which we do not believe should

be the intent of CMS. DSH and IME funds support special purposes not relevant to ACOs and should be excluded.

III. Assignment of Medicare Beneficiaries

Mercy supports the use of tax identification numbers (TINs) as an organizing concept for ACOs. Consistent with the beginning of the PGP Project, the assignment of Medicare beneficiaries should then start with the TIN of the organization providing a plurality of the visits with further assignment to a primary care provider. It is our recommendation that the plurality of visits be measured on Evaluation and Management Codes (E&M Codes) excluding hospital emergency visits and urgent care visits.

The definition of primary care providers should be expanded to include advanced practitioners such as Advanced Nurse Practitioners and Physicians' Assistants. We also suggest that such advanced practitioners be issued a National Provider Identifier ("NPI") to assist with the assignment to an ACO.

We support the expanded definition set forth with respect to Pioneer ACOs which allows assignment to certain specialists (nephrology, rheumatology, endocrinology, pulmonology, neurology, and cardiology) provided the Medicare beneficiary has other primary care services for E&M Codes of less than 10%. We also suggest including specialists in geriatrics, oncology and pediatrics.

Although we support the goal of "meaningful use" adoption of electronic health records, we recommend not requiring meaningful use of EHR by 50% of ACO primary care participants at this time to encourage greater participation in the ACO Program. Under the PGP Project, meaningful use of an EHR was not required and we expect numerous high-quality providers do not yet have access to or enough experience with an EHR to achieve meaningful use. Provided an ACO can meet the reporting requirements set forth by CMS, meaningful use of EHR should not be required.

To the extent possible, we believe CMS should assign Medicare Beneficiaries to an ACO on a prospective basis. A key factor in achieving the three-part aim of the ACO is direct interaction with individual beneficiaries to better manage their individual care needs and to improve their health. Retroactive assignment of beneficiaries does not enable an ACO to do this important work upfront. An adjustment period during the first year of the ACO Agreement would allow for beneficiaries assignment modifications as needed.

If Medicare Beneficiaries assigned to an ACO seek care outside of the ACO that exceeds an established monetary threshold, or opt not to allow their health or claims data to be shared with the ACO, we suggest that such Medicare beneficiaries be excluded for the cohort of the ACO. To hold an ACO

accountable for the cost and quality of care for such Medicare beneficiaries provides a significant disincentive to participate in the ACO Program.

We believe the requirement for how Medicare beneficiaries opt out of the program should be clarified or revised. Currently, an ACO is responsible for providing advance notice and meaningful opportunity for opting out although it will have no knowledge of who relevant beneficiaries are for a period of almost two years. Additional clarification is needed for items such as the following: (i) does every ACO provider need to post the notice; (ii) at every visit / annually / every three years; (ii) does an opt out last all three years of the Program; (iv) if a beneficiary is seeing providers from two separate ACOs and is inconsistent on opting out, how is the inconsistency resolved; (v) what is the mechanism for notifying the CMS of the opt out; and (vi) does opting out of the information exchange eliminate that beneficiary from assignment to an ACO.

IV. Quality Measures

We note that the number of quality measures reported under the PGP Project has grown to 32 measures in year 5 and will grow to 45 measures under the two-year transition period. Many of these measures were not readily available in an electronic format, so we had to build an infrastructure to collect and report on each measure.

In order to encourage the formation of ACOs, we recommend that CMS reduce the number of measures to a more manageable size and focus on outcomes measures in the ambulatory setting, not process or inpatient measures. Further, we recommend that additional measures not be added to the current set during the initial three-year program. Fewer measures could be required of ACOs that opt for risk only in year 3 (or no risk of such an option is provided) while additional measures could be required of Pioneer ACOs. We also support adopting measures that are routinely documented in electronic health records for ease of reporting.

Quality scores should be attainable and ACOs that achieve consistently high quality scores should not be penalized either in the calculation of shared savings or in the calculation of shared losses.

V. Administration of ACOs

We believe the proposed ACO governance and management rules impose numerous prescriptive requirements that are not necessary for ACO success as shown by the PGP Project. In addition, the intent of the requirements may be satisfied by less prescriptive and more effective means. For example, we have found community round tables and patient focus groups and e-panels to be a better means for obtaining the perspective and feedback of Medicare

beneficiaries on our performance than requiring their presence as part of the governing board. Moreover, since CMS appears to be supporting the use of the ACO structure for commercial patients under the Pioneer ACO proposal, these strict governance requirements may inhibit such expansion. Instead we recommend that CMS include in the application process that ACOs set forth how they intend to receive feedback from Medicare beneficiaries and the Community as part of their operating plan to achieve the three-part aim. Similarly, assuming the three-part aim of the ACO is being pursued and the results in quality and savings are being reported as required, we fail to see how the governance requirements are necessary. State law requirements should apply to governance rules, not ACO requirements.

In the proposed regulations, CMS requests a wide variety of detailed information in the application process. We believe CMS should require a work plan that addresses the overall approach of the ACO to achieving its goals, but allow flexibility for the ACO to refine its general work plan to address day-to-day operations as it evolves. We encourage CMS to develop a list of topics to be covered by the work plan but allow ACO applicants flexibility in describing their overall approach rather than provide detailed processes and timelines. We also encourage CMS to work with the related agencies like the FTC/DOJ and IRS to be sure the ACO application process to reach a final approval for participation does not exceed 3 months.

The movement of healthcare providers into or out of a community and into or out of a given organization needs to be better addressed in the ACO regulations. Greater flexibility appears to be included for Pioneer ACOs as proposed. We recommend consideration be given to changes of ACO participants of up to 10% annually with additional changes in excess of 10% to be negotiated as an amendment to the ACO Participation Agreement to avoid confusion and uncertainty.

Mercy supports the need to provide patients with a clear understanding of the services available to them but believes CMS should issue guidelines and formats for such communications rather than require that all such marketing materials (and amendments thereto) be submitted to CMS for approval. Adherence to the guidelines could then be monitored by CMS as part of its ongoing evaluation of the performance of the ACO.

ACOs should have patient identifiable data available to them of their assigned Medicare beneficiaries as soon as such assignments are made and on at least a quarterly basis thereafter. Data regarding beneficiary health status, claims history and provider utilization is critical to satisfying the three-part aim of the ACO Program as well as achieving the desired quality outcomes and shared savings.

Under the proposed ACO Program, many key determinations relevant to measuring the performance of an ACO are made exclusively by CMS without any apparent process of appeal to an independent review body. Since ACOs will be making substantial investments to participate in the ACO Program, we believe a fair process of appealing CMS's determinations should be included.

We also recommend that CMS adopt a process and opportunity for adjudication of issues where CMS or other government agencies have created barriers to an ACO's ability to improve care or any of the other parts of the three-part aim of the ACO Program.

VI. Other Concerns

The sharing of clinical data and outcomes among ACO participants will be critical to achieving the aim of better care for Medicare beneficiaries under the ACO Program. Some of this data will include patient identifiable information and may include assessments of the care provided and means for improving care. We recommend that CMS include specific protection of the confidentiality of the shared data and any analysis thereof from discovery by third parties rather than compelling ACOs to determine whether such information may remain confidential under other laws and rules such as those applicable to patient safety organizations, peer review processes, and attorney-client privilege or work product.

Similarly, we recommend that ACOs be exempt from malpractice laws so that the burden of malpractice insurance and litigation costs are not added to the already significant cost of forming and maintaining an ACO. Such protections to ACOs will not preclude patients from pursuing claims for malpractice against ACO participants or from seeking discovery with respect thereto directly from such participants under existing laws.

VII. Additional Comment Letters

Attached for your information are the related comment letters we are sending to CMS and OIG, to the IRS and to the FTC/DOJ regarding their respective proposed waivers and policy statements. Please note that we believe that the ACO Program to be administered by CMS has sufficient accountability and transparency safeguards to protect both Medicare beneficiaries and the Medicare Program to supplant the traditional legal safeguards contained in these other laws and regulations. Therefore, we recommend general waivers for ACOs and ACO participants from such laws and regulations rather than piecemeal, issue-by-issue waivers, as proposed.

We also respectfully point out that CMS appears to encourage the extension of ACO-like shared savings programs to patients covered by other payers as

evidenced in the proposed Pioneer ACO model. We support this encouragement but note that the proposed waivers and policy statements do not extend beyond ACO activities on behalf of Medicare beneficiaries. This is an important clarification necessary for the formation of an ACO that can address the care of more than just Medicare beneficiaries as desired by CMS.

We thank you for the opportunity to provide these comments and again would like to express our appreciation to CMS for the opportunity to have St. John's Clinic in Springfield, Missouri participate in the PGP Project. We look forward to continuing to work with CMS to make the three-part aim of ACOs a reality.

Sincerely,

Lynn Britton
President and Chief Executive Officer