September 1, 2016

Andrew M. Slavitt, Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS–1656–P  
P.O. Box 8013  
Baltimore, MD 21244–1850

RE: CMS–1656–P – Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program

Submitted electronically via www.regulations.gov

Dear Mr. Slavitt,

UnityPoint Health ("UPH") appreciates this opportunity to provide feedback on the proposed rule. UPH is one of the nation’s most integrated healthcare systems. Through more than 30,000 employees and our relationships with more than 280 physician clinics, 32 hospitals in metropolitan and rural communities and home care services throughout our 9 regions, UPH provides care throughout Iowa, Illinois and Wisconsin. On an annual basis, UPH hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 4.5 million patient visits.

**Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider**

Section 603 of the Bipartisan Budget Act of 2015 changed the reimbursement structure for off-campus provider-based departments (PBDs). In general, existing off-campus PBDs are eligible for reimbursement under the Outpatient Prospective Payment System (OPPS), while new off-campus PBDs must seek reimbursement under a separate fee schedule. In this proposed rule,
CMS defines whether certain items and services furnished by a given off-campus PBD to be considered excepted and continue to be paid under the OPPS, establishes the requirements for an off-campus PBD to maintain excepted status, and describes the applicable payment system for non-excepted items and services. For excepted facilities, we respectfully offer comments related to off-campus PBD status and relocation as well as the expansion of clinical services.

- **Off-Campus PBDs**

  **Proposed Rule:** To bill under the OPPS on and after January 1, 2017, an off-campus PBD must have been billing prior to November 2, 2015, under the OPPS for covered services. These PBDs are considered excepted. For non-excepted off-campus PBDs, these facilities would bill under the Medicare Physician Fee Schedule.

  **Comments:** We request that CMS recognize excepted status for off-campus PBDs under construction prior to November 2, 2015, to honor prior and ongoing commitments and investments in these new facilities. Long before the enactment of Section 603, UPH had engaged in extensive planning, obtained regulatory approval, and broke ground on a facility to include an off-campus PBD in Ankeny, Iowa. This facility site is located 14.51 miles from UnityPoint Health - Iowa Lutheran Hospital (Lutheran) in Des Moines, Iowa. The PBDs are established service line and is billing on campus, and the new off-campus address has been secured. Among the tenants within this new facility are Surgery, Pharmacy and Laboratory PBDs. The Surgery PBD is just over 13,000 square feet, is projected to have an initial caseload of 1,500 patients, and is targeting minor orthopedic procedures, such as knee arthroscopy, ACL repairs, and shoulder and rotator cuff repairs. By shifting this surgical caseload from Lutheran’s main campus, it will decrease patient wait time for elective surgeries at the main campus and off-site facilities as well as offer a more convenient location for patients residing in the high growth region of northwest Polk county and surrounding areas.

UPH has made substantial investments of time and resources to the Ankeny project. Our project and the start of construction predated the abrupt revision to the Medicare off-campus PBD reimbursement structure. In particular:

- **2003:** Iowa Lutheran Hospital purchased the land subject of this construction project for future expansion efforts in the city of Ankeny.
- **June 2014:** Business plan submitted to the UPH Finance Committee.
- **October 27, 2014:** The Iowa Department of Public Health authorized the extension of Iowa Lutheran Hospital’s outpatient surgery services to a freestanding location in Ankeny.
- **October 13, 2015:** Construction began (i.e. date of ground breaking) on UnityPoint Health Ankeny Medical Park facility.
- **February 2015:** Projected opening of Pharmacy and Laboratory PBDs at the Ankeny facility.
- **March 2017:** Projected opening of Surgery PBD at the Ankeny facility.
To differentiate treatment for facilities under construction like ours, CMS disregards our ongoing deliberate and thoughtful planning, approval and construction progress required to operationalize an off-campus PBD. Historically, CMS has protected both existing facilities and those under construction when passing moratoriums on new facilities, including recent changes to Medicare payment for physician-owned hospitals and long-term care hospitals. Similar treatment for facilities billing for services and facilities under construction appreciates the significant development and decision-making process underlying the establishment of an off-campus PBD.

- **Relocation of Excepted Off-Campus PBDs**
  
  **Proposed Rule:** Excepted off-campus PBDs and the items and services that are furnished by such departments would no longer be excepted if the excepted off-campus PBD moves from the physical address that was listed on the provider’s hospital enrollment form as of November 1, 2015. CMS is seeking comment regarding circumstances beyond the hospital’s control where an excepted off-campus PBD must relocate as well as whether CMS should develop a clearly defined, limited relocation exception process.

  **Comments:** Restricting the relocation of off-campus PBDs to disaster situations is overly restrictive. To promote patient-centered care delivery, we urge CMS incorporate a more flexible standard to not take into account numerous factors, including loss of a lease. Over the past 30 years, UPH has relocated and even combined off-campus PBD locations due to patient caseloads, geographic needs, and financial efficiency (rent affordability). This continued relocation flexibility is required for UPH to meet patient needs and efficiently provide services in the future. We recommend that CMS adopt relocation criteria similar to that used for Critical Access Hospital (CAH) relocation. CAH relocation decisions require CMS approval and documentation that the new site/facility:

  (i) Serves at least 75% of the same service area that it served prior to its relocation;

  (ii) Provides at least 75% of the same services that it provided prior to the relocation; and

  (iii) Is staffed by 75% of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.

- **Expansion of Clinical Family of Services at an Excepted Off-Campus PBD**
  
  **Proposed Rule:** Items and services that are not part of a clinical family of services furnished and billed by the excepted off-campus PBD after November 1, 2015 would not be payable under the OPPS. CMS is not limiting the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish.

  **Comments:** We opposed the bright-line restriction prohibiting the inclusion of any new clinical family of services at the excepted off-campus PBD. This proposal does not
accommodate any need by the hospital to coordinate care and services for clinical services
that do not fall within the APC clinical family of services. For instance, combining clinical
oncology with radiation oncology makes good clinical sense to patient care, yet would not be
allowable within the confines of the proposed rule. UPH supports the use of criteria similar
to the CAH relocation criteria listed above, which enables the inclusion of new services as
long as 75% is the same as contemplated prior to November 2, 2015.

We encourage CMS to clarify the definition of off-campus PBDs to except facilities already under
construction and to ease proposed rules related to relocation and expansion of clinical services.
To discuss our comments or for additional information on any of the addressed topics, please
contact Sabra Rosener, Vice President and Government Relations Officer, Government and
External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,

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