December 28, 2015

Response to Request for information
CY 2016 Physician Fee Schedule (PFS) Policy Revisions

Federal Register Notice of November 16, 2015 [FR Doc #: 2015-28929]
Specific reference: Section II, 2.a. (direct practice expense methodology) page 70891

RE: Pharmacist Labor Cost Association with Direct Practice Expense Calculations

To Whom It May Concern:

The American College of Clinical Pharmacy (ACCP) appreciates the opportunity to provide information in response to questions posed in the above-referenced notice concerning “…the typical clinical labor costs involving pharmacists for particular PFS services.” ACCP is the nation’s third largest pharmacist professional organization, providing leadership, education, advocacy, and resources that enable clinical pharmacists to achieve excellence in patient care practice and research. ACCP’s membership is composed of almost 17,000 clinical pharmacists, residents, fellows, students, scientists, educators and others who are committed to excellence in clinical pharmacy practice and evidence-based pharmacotherapy.

Our response and the information provided are based upon information provided to us by established practices and colleagues who are actively engaged in team-based primary care and specialty medical practices within the United States. The information reflects a combination of aggregated information of a proprietary nature as well as publicly available data from sources such as the Bureau of Labor Statistics (BLS) and the Health Resources and Services Administration (HRSA).

Importantly, the information is presented in the context of an interprofessional and integrated practice framework and structure. It is grounded in a series of established definitions, professional practice standards, and policy documents that more fully define the “scope” (i.e., the “work/labor activity”) of medication-related care – now commonly referred to as comprehensive medication management (CMM) - that is being delivered by clinical pharmacists within physician/clinic practices. In this regard, the “labor costs” associated with this specific “work” are the most relevant to the information request that has been presented by CMS in order to more fully understand the pharmacist-specific labor component of the practice expense [PE] calculation. A list of these standards, definitions, and policy clarifications is provided at the end of this communication.

It is our view that generalized salary data for pharmacists and information from traditional pharmacy practice structures not having a professional/business relationship (employment, consulting, collaborative practice agreements and/or clinical credentialing/privileging) for such services between/among providers would likely be unhelpful for purposes of calculating pharmacist labor costs for inclusion in the PFS PE formula.
ACCP provides the following information for current and future considerations to support the evolving refinement of PFS policies for integrated and value-driven medical practices of all types. Such information should be broadly applicable whether or not practices are engaged in any specialized initiatives, such as those currently supported by CMMI, that involve pharmacists in team-based patient care activities now or in the future.

**Scope/Philosophy of Practice:**

The scope of practice/frame of reference for pharmacist “work” in the medical/integrated practice setting is reflected in available documents that principally include:

- ACCP standards of practice (Standards II and III);
- Patient-Centered Primary Care Collaborative (PCPCC) resource guide on CMM – Appendix A;
- Joint Commission of Pharmacy Practitioners (JCPP) process of care document and;
- Consensus definition of medication therapy management services (MTM) developed and endorsed by the pharmacy profession in 2004; and
- Communications in 2014 between the American Academy of Family Physicians (AAFP) and then-administrator of CMS Marilyn Tavenner.

These standards and definitions should not be equated to or confused with the much narrower benefit design definitions of “MTM” within Part D drug benefit programs as operationalized under various and assorted Medicare Part D plan designs.

The successful accomplishment of the scope of practice activities about which CMS appears to be seeking labor cost information requires, from ACCP’s perspective, the existence of either formal employment or consulting arrangements, a formally established (i.e., regulatory authorization) collaborative practice agreement or similarly empowering contract, or credentialing/privileging mechanism to facilitate the efficient and responsible accomplishment of this work. It is in this context that a more accurate and realistic accounting for the “practice expense” contribution of the clinical pharmacist’s work can be obtained.

**General Labor Cost Calculations:**

Based on both public and private data sources, a reasonable and defensible approximation of annual salary including generally applied fringe benefit calculations for a (clinical) pharmacist practicing in integrated or imbedded direct patient care practices is in the range of $140-155 thousand per year. In comparison, the current BLS annual mean salary for all pharmacists not including benefits is $118 thousand. This information represents a fundamental benchmark from which calculations may be made concerning the “labor costs” of pharmacists across the spectrum of the profession.

It is important to appreciate in the context of labor costs that clinical pharmacists are more extensively educated and trained than any other “non-provider” member of a typical patient care team. Information from a range of integrated practices indicates that labor budgets and justifications for clinical pharmacists in imbedded private-sector practices may be as much as twice that of a RN clinical coordinator or staff registered nurse and almost four times that of a typical medical assistant. In some cases, salary costs of pharmacists can approach those of newly hired physicians and some experienced NPP’s.

It is therefore essential to evaluate pharmacist labor costs calculations in the context of the scope and intensity of the work to be performed as described below. It is also important to remember that other components of PE associated with non-labor costs (rent, utilities, etc.) are impacted by the work of a clinical pharmacist within the practice’s business operations, information systems, and physical structure as well.
Practice Structure – Imbedded/Employed:

Practice Work of Clinical Pharmacists –

As previously mentioned, a clinical pharmacist within an integrated medical practice is responsible for and accomplishes significant portions of the medication management work - initiation, modification, discontinuation, monitoring, documentation, follow up, etc., to achieve clinical goal attainment for patients’ medication use - that would otherwise be the work/responsibility of (and consume the time of) the physician or NPP in the absence of the clinical pharmacist.

The frequency and intensity of CMM services is inevitably practice-specific, and driven by the intensity and frequency of medication-related care necessary for the specific practice’s population - or portion of it – for which CMM services are important and desirable. In general, however, the pharmacist labor expense, would be slightly less (although accounted for in the PE component calculation under existing payment rules) than the physician work expense that could be associated with the same sub-set of clinical work. This is primarily because the numbers of patients requiring the direct patient care activities of the clinical pharmacist will constitute something less than 100 per cent of the patients being cared for by the physician/NPP’s practice.

It is potentially helpful to conceptualize the work of the clinical pharmacist in this context and in such practices NOT as physician-extender (or NPP-extender) work but rather, operationally, as physician/NPP “efficiency enhancement” work. In operation, it reflects an off-loading to the qualified clinical pharmacist of specific and discreet components of “medical practice” activity currently presumed by CMS (in its payment policies) to be physician work in the achievement of quality medication use for which the practice (through both physician work and PE calculations currently) receives payment under current PFS policy.

Relevant Code/Service Descriptions

Given the description of CMM practice provided in the foregoing comments, we believe that the principal and relevant HCPCS/CPT codes that would be commonly associated with this practice, and therefore applicable to labor cost calculations under the PE component include, but may not be limited to, the following:

- The existing and recognized pharmacist services time-based codes in the 99605-07 series. We would specifically note that these codes are NOT confined for use solely within Part D MTM programs, and can provide a framework for pharmacist-specific coding/documentation by a range of benefit designs and payment structures;
- Significant portions of the range of relevant Evaluation & Management codes in the 99211-99215 series, which best describe many of the elements of medication management activities that occur in a typical/broader medical office visit; and
- Emerging codes reflecting TCM, CCM and other care coordination, telephonic, and team-based care activities that are in development or under consideration.
Use of these codes has always been and will continue to be relevant in the current CMS regulatory policy framework supporting “incident to” documentation and billing activities, which reflect the most common current approach. We believe this continues to be true regardless of the various initiatives and innovation activities currently underway within CMMI.

Again, we appreciate the opportunity to provide this information in response to the request outlined in the proposed final rule and trust that it will be helpful to your deliberations. We welcome the opportunity for further dialogue on this topic at any time in the future to assist in better understanding the effective incorporation of clinical pharmacists into evolving physician practices and integrated care delivery systems.

Sincerely,

[Signature]

Associate Executive Director

cc: Michael S. Maddux, Pharm.D., FCCP

**Resources Mentioned in the RFI Response:**

Standards of Practice for Clinical Pharmacists – American College of Clinical Pharmacy – 2014

Integrating comprehensive medication management to optimize patient outcomes – Patient-Centered Primary Care Collaborate (PCPCC) - 2012

Pharmacists’ Patient Care Process – Joint Commission of Pharmacy Practitioners (JCPP) – 2014

Medication Therapy Management Services – Definition and program criteria - 2004
http://www.accp.com/docs/positions/misc/MTMDefn.pdf

Correspondence between AAFP and CMS regarding incident-to billing/services of pharmacists –
http://www.accp.com/docs/positions/misc/AAFP%20MTM%20Letter%20to%20CMS%5E2.pdf