TABLE 14—CY 2018 PROPOSED RULE—INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS—Continued

CPT/HCPCS codes	Item name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
30140, 30901, 30903, 30905, 30906, 31231, 31237, 31238, 43197, 43198.	Atomizer tips (disposable).	SL464	0.00	2.66	.....	1	625,876
36514	tubing set, plasma exchange.	SC085	173.33	273.66	58	1	1,237
36514, 36516	ACD–A anticoagulant	SJ071	6.58	7.10	8	1	2,517
none (formerly in deleted code 36515).	kit, apheresis treatment.	SA072	140.00	243.33	74	1	22
36522	kit, photopheresis procedure.	SA024	858.00	1598.00	86	1	25
36522, 96567, 96910, 96912, 96913, 96920, 96921, 96922, 96X73, 96X74.	goggles, uv-blocking	SJ027	2.30	4.1	78	1	697,047
88360, 88361	Antibody Estrogen Receptor monoclonal.	SL493	14.00	14.47	3	3	209,384
95004, 95017, 95018	negative control, allergy test.	SH101	5.08	5.17	2	2	10,036,050
95004, 95017, 95018	positive control, allergy test.	SH102	17.28	26.12	51	6	10,036,050
95250	sensor, glucose monitoring (interstitial).	SD114	29.50	53.08	80	19	26,205
95250	glucose continuous monitoring system.	EQ125	2465.00	1170.54	−53	5	26,205
993X1, G0249	test strip, INR	SJ055	21.88	5.66	−74	2	1,265,540

I. Evaluation & Management (E/M) Guidelines and Care Management Services

In recent years, we have sought to recognize significant changes in health care practice, especially innovations in the active management and ongoing care of chronically ill patients. We have been engaged in an ongoing incremental effort to identify gaps in appropriate coding and payment for care management/coordination, cognitive services and primary care within the PFS. This has included working with the CPT Editorial Panel (CPT) to develop and value (or revalue) the following service codes:

- Transitional care management (TCM) services (2013).
- Chronic care management services (CCM) (2015, 2017).
- Behavioral health integration (BHI) services (2017).
- Assessment/care planning services for cognitive impairment (2017).
- Prolonged E/M services without direct patient contact (2017).

In response to public feedback regarding the initial implementation of TCM and CCM, in the CY 2017 PFS final rule (81 FR 80225 through 80256), we finalized significant administrative burden reduction for CCM and focused on limiting as much as possible the ways in which Medicare's rules differed from the CPT guidance that generally applies for all payers. We also worked with the CPT Editorial Panel and other stakeholders to develop coding and improve payment accuracy for BHI, cognitive impairment assessment/management, and prolonged services. In the CY 2017 PFS final rule (81 FR 80255), we also reiterated our commitment to addressing disparities for individuals with disabilities and advancing health equity, and noted that we will continue to explore improvements in payment accuracy for services furnished to individuals with disabilities. We look forward to continued work with stakeholders to ensure that the coding and valuation of these services accurately reflects the resource costs involved in furnishing these services. We are soliciting public comments on ways we might further reduce administrative burden for these and similar services under the PFS.

1. E/M Guidelines

a. Background

Most physicians and other billing practitioners bill patient visits to the PFS under a relatively generic set of codes that distinguish level of complexity, site of care, and in some cases between new or established patients. These codes are called Evaluation and Management (E/M) visit codes. For example, there are generally three levels of hospital and nursing facility inpatient E/M visit codes, and five levels of office or hospital outpatient E/M visit codes, that vary based on complexity. The latter also distinguish whether or not the patient is new to the billing practitioner.

Billing practitioners must maintain information in the medical record to document that they have reported the appropriate level of E/M visit code. CMS maintains guidelines that specify the kind of information that is required to support Medicare payment for each level. According to these documentation guidelines, there are three key components to selecting the appropriate level:

- History of Present Illness (HPI or History);
- Physical Examination (Exam); and
- Medical Decision Making (MDM).

There are two versions of the documentation guidelines, commonly referenced based on the year of their

release (the ''1995'' and ''1997'' guidelines), available under downloads on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* The most substantial differences between the two sets of guidelines pertain to requirements for the physical exam. The two versions have a slight difference in requirements for documenting the history, and no difference in requirements for MDM. In documenting a given E/M service, practitioners must use one version of the guidelines or the other, with one exception related to extended histories (see the Evaluation and Management Services guide available on the CMS Web site at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf*). These guidelines are very similar to guidelines within the CPT codebook for E/M visits. We provide an example of how the guidelines distinguish between level 2 and level 3 visits in Table 15.

Stakeholders have long maintained that both the 1995 and 1997 guidelines are administratively burdensome and outdated with respect to the practice of medicine, stating that they are too complex, ambiguous, and that they fail to distinguish meaningful differences among code levels. In general, we agree that there may be unnecessary burden with these guidelines and that they are potentially outdated, and believe this is especially true for the requirements for the history and the physical exam. The guidelines have not been updated to account for significant changes in technology, especially electronic health record (EHR) use, which presents challenges for data and program integrity and potential upcoding given the frequently automated selection of code level.

While CMS conducts few audits on E/M visits relative to the volume of PFS services they comprise, we have repeatedly heard from practitioners that compliance with the guidelines is a source of significant audit vulnerability and administrative burden. Our prior attempts to revise the guidelines met with a lack of stakeholder consensus and support, which contributed to the current policy that allows practitioners to use either the 1995 guidelines or 1997 guidelines, resulting in further complexity in determining or selecting the applicable requirements.

b. E/M Guidelines Public Comment Solicitation

We continue to agree with stakeholders that the E/M documentation guidelines should be substantially revised. We believe that a comprehensive reform of E/M documentation guidelines would require a multi-year, collaborative effort among stakeholders. We believe that revised guidelines could both reduce clinical burden and improve documentation in a way that would be more effective in clinical workflows and care coordination. We also think updated E/M guidelines coupled with technological advancements in voice recognition, natural language processing and user-centered design of EHRs could improve documentation for patient care while also meeting requirements for billing and population health management. We recognize that achieving the goal of reduced clinician burden and improved, meaningful documentation for patient care will require both updated E/M guidelines, as well as changes in technology, clinician documentation practices and workflow. We are seeking input from a broad array of stakeholders, including patient advocates, on the specific changes we should undertake to reform the guidelines, reduce the associated burden, and better align E/M coding and documentation with the current practice of medicine. We are specifically seeking comment on how we might focus on initial changes to the guidelines for the history and physical exam because we believe documentation for these elements may be more significantly outdated, and that differences in MDM are likely the most important factors in distinctions between visits of different levels. We are also specifically seeking comment on whether it would be appropriate to remove our documentation requirements for the history and physical exam for all E/M visits at all levels. We believe medical decision-making and time are the more significant factors in distinguishing visit levels, and that the need for extended histories and exams is being replaced by population-based screening and intervention, at least for some specialties. In addition, an increase in the utilization of EHRs, and to some extent, shared health information via EHRs, may have changed the character of extended patient histories since the guidelines were established. As long as a history and physical exam are documented and generally consistent with complexity of MDM, there may no longer be a need for us to maintain such detailed specifications for what must be performed and documented for the history and physical exam (for example, which and how many body systems are involved). We are seeking comment on whether clinicians and other stakeholders believe removing the documentation requirements for the history and physical exam would be a good approach.

While we believe MDM guidelines may also need to be updated, we believe in the nearer term it may be possible to eliminate the current focus on details of history and physical exam, and allow MDM and/or time to serve as the key determinant of E/M visit level. We are seeking public comment on this approach. We are also seeking comment on how such reforms may differentially affect physicians and practitioners of different specialties, including primary care clinicians, and how we could or should account for such effects as we examine this issue. We note, however, that there may still be clinical or legal reasons for individual practitioners to document an extended history or physical exam (for example, where there are negative findings for certain body systems in support of differential diagnosis). We are additionally seeking comment on whether CMS should leave it largely to the discretion of individual practitioners to what degree they should perform and document the history and physical exam. We also welcome comments on specific ideas that stakeholders may have on how to update MDM guidelines to foster appropriate documentation for patient care commensurate with the level of patient complexity, while avoiding burdensome documentation requirements and/or inappropriate upcoding.

We note that through letters, meetings, public comment letters in past rulemaking cycles, and other avenues, we have heard from many stakeholders that the E/M code set itself is outdated and needs to be revised. For example, some stakeholders recommend an extensive research effort to revise and revalue E/M services, especially physician work inputs (see 81 FR 46200). In prior rulemaking cycles, we acknowledged the limitations of the current E/M code set and agree that the structure of the underlying code set and its valuation relative to other PFS services are also important issues that we expect to continue to explore, though we are immediately focused on revision of the current E/M guidelines in order to reduce unnecessary administrative burden.

2. Care Management Public Comment Solicitation

We continue to be interested in the ongoing work of the medical community and other stakeholders to refine the set of codes used to describe care