Before the
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
Baltimore, MD 21244

In the Matter of )
42 CFR Parts 403, 405, 410, et al. ) CMS–1612–P
Medicare Program; Revisions to Payment )
Policies Under the Physician Fee Schedule, )
Clinical Laboratory Fee Schedule, Access to )
Identifiable Data for the Center for )
Medicare and Medicaid Innovation Models )
& Other Revisions to Part B for CY 2015; )
Proposed Rule )

COMMENTS OF THE TELECOMMUNICATIONS INDUSTRY ASSOCIATION

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September 2, 2014

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1600-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments of the Telecommunications Industry Association on the Center for Medicare and Medicaid Services’ Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015 [CMS-1612-P]

I. Introduction and Statement of Interest

The Telecommunications Industry Association (“TIA”) hereby submits input to the Department of Health and Human Service’s Centers for Medicare & Medicaid Services (“CMS”) request for input on proposed Medicare program revisions to payment policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, and other revisions to Part B for CY 2015 (“Proposed PFS”).

TIA is a trade association representing nearly 400 global manufacturers, vendors, and suppliers of information and communications technology (ICT), and engages in policy efforts specific to health ICT to promote a modern healthcare system that leverages innovative technologies to transform the way care is delivered and implemented. Many of TIA’s member companies develop, manufacture, and supply health information technologies and medical devices, producing the tools that allow patients and healthcare providers to connect virtually anytime, anywhere.

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1 CMS, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015, 79 F.R. 40318-40540 (Jul. 11, 2014).
II. The Health Care System of the Future Should Realize the Potential of Telehealth and Remote Patient Monitoring

Generally, TIA members are long-time supporters of enhanced telehealth services and we believe that remote connectivity has become an essential part of modern medical care. A 21st century healthcare system must leverage innovations in communications technologies. However, outdated regulations that have restricted the use of telehealth have long been a hindrance to progress in this space. As a notable example, Section 1834(m) of the Social Security Act has resulted in arduous restrictions on telehealth services (see 42 CFR § 410.78). The ICT manufacturer, vendor, and supplier community urges for CMS (and other federal agencies) to utilize every opportunity to work towards a connected healthcare system by removing barriers to the utilization of advanced technologies. For example, a broad cross-section of stakeholders in the healthcare space have joined TIA in urging HHS Secretary Burwell to waive 1834(m) restrictions on Accountable Care Organizations in the Medicare Shared Savings Program.2

Remote patient monitoring of patient-generated health data (PGHD) is increasingly being proven as an important aspect of any healthcare system. The known benefits of remote patient monitoring services include improved care, reduced hospitalizations, avoidance of complications and improved satisfaction, particularly for the chronically ill.3 In addition, the use of virtual chronic care management by the Department of Veterans Affairs resulted in a substantial decrease in hospital and emergency room use.4 There is also a growing body of potential cost savings, noted most recently by a study predicting that remote monitoring will result in savings of $36 billion globally by 2018, with North America accounting for 75% of those savings.5 Simply stated, integrating the use of PGHD may also engage some patients in their own care, which can lead to improved lifestyle choices and improve overall health.6

2 See http://bit.ly/1na1UrA.
We urge CMS to allow for the full range of available technologies to improve quality, safety, efficiency, and reduce health disparities by engaging patients and families while improving care coordination, population and public healthcare. Policies must be in place that enable greater use of these dynamic solutions and promote greater development and opportunities for healthcare delivery. While national and global efforts to develop, integrate, and utilize innovative technologies that enable eHealth and telemedicine have allowed this industry to mature, we must continue looking for ways to maximize the potential of health ICT.

In comments below, TIA urges CMS to:

- Plainly communicate standards for the mandatory use of electronic health information technology in providing Chronic Care Management ("CCM").
- Ensure that its CCM eligibility requirements are based on objective criteria.
- Assign to CCM a Practice Expense Relative Value Unit of 0.93 and a Malpractice Expense Relative Value Unit of 0.09. In the alternative, CMS should clarify that CCM furnished by a Rural Health Clinic or Federally Qualified Health Center constitutes a Non-Rural Health Clinic or Non-Federally Qualified Health Center Service for which the Rural Health Clinic or Federally Qualified Health Center may bill separately. CMS should also permit CCM and Transitional Care Management furnished By a Rural Health Center or Federally Qualified Health Center to be furnished "incident to" under General Supervision.
- Provide a model agreement for beneficiaries to consent to the provision of CCM.
- Create an additional separate code for CCM incorporating electronic remote patient monitoring to which a higher Practice Expense RVU is assigned.
- Account for remote patient monitoring in the new proposed Healthcare Common Procedure Coding System Code.
III. TIA’s Comments Regarding CMS’ Proposed Approach to Chronic Care Management

Based on our long-held views described above, in 2013 TIA supported the proposal from CMS to create a new reimbursement for non-face-to-face complex CCM.7 We believe that CMS’ general activity in this space reflects the widely-held view that enhanced telemedicine and other related applications, including the remote monitoring of PGHD (patient biometric and physiological data,) that have demonstrated better quality healthcare for patients, better access to medical specialists, and lower healthcare costs.8 Specific to the Proposed PFS’ approach to CCM, TIA urges for CMS to move forward consistent with the following views.

A. CMS Should Plainly Communicate Standards for the Mandatory Use of Electronic Health Information Technology In Providing Chronic Care Management.

Because not all providers and other licensed clinicians have the capability today to deliver CCM based on requirements for new staff, additional duties, etc., CMS should strive to establish and employ new and improved processes that will facilitate CCM to its full potential. This is particularly true in the case of CMS’ proposed requirements for the use of an “electronic health record” or “other health IT” or “health information exchange platform” in providing CCM that will demand up front from providers either the acquisition of new EHR technology or the alteration of EHR technology already in use to ensure proper billing for CCM. In this particular circumstance and others, it is particularly important that as much certainty be given to providers in cases such as these so that CMS’ policies do not inadvertently deter the widespread use of new and more efficient CCM services.

In the Proposed PFS, TIA believes that CMS’ definition of its health IT requirements should be improved to provide this needed certainty. First, the Proposed PFS sets its CCM health IT requirements as:

CCM services must be furnished with the use of an electronic health record or other health IT or health information exchange platform that includes an electronic care plan that is accessible to all providers within the practice, including being accessible to those who are furnishing care outside the normal business hours, and that is available to be shared electronically with the care team members outside of the practice.9

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7 TIA’s previous comments to CMS are available at http://www.tiaonline.org/sites/default/files/pages/TIA_Comments-ProposedMedicareProgramRevisions_CMS-1600-P-090613.pdf.

8 For example, the American Telemedicine Association offers numerous case studies that demonstrate the value of telemedicine. See http://www.americantelemed.org/learn/telemedicine-case-studies.

9 Proposed PFS at 40367.
Further, CMS subsequently provides the following on how a provider should satisfy specific Health IT certification standards:

To ensure all practices have adequate capabilities to meet electronic health record requirements, the practitioner must utilize EHR technology certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. At a minimum, the practice must utilize EHR technology that meets the certification criteria adopted at 45 CFR 170.314(a)(3), 170.314(a)(4), 170.314(a)(5), 170.314(a)(6), 170.314(a)(7) and 170.314(e)(2) pertaining to the capture of demographics, problem lists, medications, and other key elements related to the ultimate creation of an electronic summary care record.10

TIA believes that it is crucial for CMS to clarify the relationship between these two separate pieces of text within the Proposed PFS, one referring to the requirement for an electronic care plan, and the other referring to an electronic summary care record. We encourage CMS to determine whether the former and latter are two distinct requirements, or whether the latter discussion of an electronic summary care record is meant to clarify the certification criteria that must first be met in order to satisfy the former.

- If CMS’ approach is that both pieces of text are separate requirements, TIA strongly urges for CMS to put forth clear and objective criteria for an electronic care plan that providers will be able to use to ensure that their health IT satisfies.

- If the approach is that the language on electronic summary care records determines the requirements in language on electronic care plans, TIA urges for CMS to clarify the language in the final rule, stating simply that CCM must be furnished using health IT that has been certified as meeting certain criteria.

10 Id.
B. **CMS Should Ensure that its CCM Eligibility Requirements are Based on Objective Criteria.**

In the Proposed PFS, CMS proposes eligibility requirements for CCM which bound the service to Medicare beneficiaries with “multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, exacerbation/decompensation or functional decline.”\(^{11}\) As proposed, decisions on whether to qualify a beneficiary for CCM would be based on a practitioner’s subjective decision as to the beneficiary chronic conditions’ level of acuity. TIA raises concern with CMS on this proposal because no objective criteria has been proposed that the practitioner would use to make such a determination.

TIA believes that it is important for CMS to provide practitioners with the ability to objectively determine a beneficiary’s chronic condition, allowing for a standardized way to characterize the condition’s risk posed. The use of objective criteria will promote consistency in the application of CMS’ policies, and will avoid the risks posed to practitioners that would provide CCM, only to have their determination of eligibility later reversed by administrative or auditing staff. In addition, because chronic conditions are typically correlated to improper management of the condition, receiving care would naturally reduce this risk factor, potentially making many beneficiaries ineligible until their condition was exacerbated due to a lack of this management. To avoid these negative results, TIA instead urges for CMS to adopt objective eligibility criteria for the determination of a beneficiary’s chronic condition that does not reference acuity level.

TIA believes that CMS may find useful guidance in this matter in the approach taken by Section 2703 of the Affordable Care Act, which, in creating a discretionary Medicaid State Plan benefit that would establish health homes to harmonize and inform care for chronic care beneficiaries under Medicaid, put forward objective eligibility criteria for determining the Medicaid health home benefit.\(^{12}\) Specifically, Section 2703 statues that health home services may be provided to beneficiaries that (1) have multiple (two or more) chronic conditions; (2) have a single chronic condition and are also at risk for a second chronic condition; or (3) have a single severe and persistent mental health condition. Notably, Section 2703 additionally provides a list of qualifying chronic conditions while also granting the HHS Secretary the ability to alter the list as deemed appropriate at a later time.

\(^{11}\) *Id.* at 40365.

\(^{12}\) PL 111-148, PL 111-152
We urge CMS to take a similar approach in its path forward on CCM eligibility requirements, and to develop objective eligibility criteria. A solid step in this direction TIA suggests is the deference to the fifteen most widespread chronic conditions in the Medicare program, already identified in CMS’ *Chronic Conditions Among Medicare Beneficiaries, Chartbook, 2012 Edition*, as it is updated.

C. **CMS Should Assign to CCM a Practice Expense Relative Value Unit of 0.93 and a Malpractice Expense Relative Value Unit of 0.09.**

In the Proposed PFS, CMS proposes a practice expense (PE) relative value unit (RVU) of 0.57 and a malpractice expense (ME) RVU of 0.04 for CCM. For the proposed practice expense RVU, CMS only directly accounts for 20 minutes of clinical time which is based on the minimum amount for non-face-to-face care management services needed to successfully bill under CCM (0.42 of the proposed 0.57 practice expense RVU).

TIA believes that limiting labor costs to 20 minutes of clinical time does not properly appreciate the additional time expended preparing for the delivery of care management services. For example, such activities include compiling and evaluation of records, keeping records on delivery of services, bringing beneficiary care plans up-to-date, and the costs of 24/7 clinician availability to address imminent chronic care needs of beneficiaries. While we strongly believe these activities should all count towards the 20 minute requirement, as proposed, none would. In addition, the joint PE/MP RVU of 0.61 that CMS proposes for CCM is also pointedly less than the combined PE/MP RVUs given to comparable services, including many services that may not be billed (e.g., home healthcare oversight, hospice care plan oversight, care plan oversight services, prolonged services without direct patient contact) during the same time period as when CCM is being billed.

In the proposed rule, CMS draws a tight analogy between CCM and transitional care management (TCM). CMS determined its proposed work RVU of 0.61 for CCM based on the work RVU for CPT 99495 (transitional care management, moderate complexity). CPT 99495 has a work RVU of 2.11, which includes both the face-to-face and non-face-to-face components of transitional care management. CMS equates the face-to-face component of CPT 99495 with CPT 99214 (level 4 established patient office or other outpatient visit). CPT 99214 has a work RVU of 1.5. CMS, therefore, subtracts 1.5 (work RVU for 99214) from 2.11 (work RVU for 99495)

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14 See Proposed PFS at Appendix B.

15 See, e.g., G0181 Home Healthcare Oversight (1.28); G0182 Hospice Care Plan Oversight (1.30); 99339 Care Plan Oversight Services (0.94); and 99358 Prolonged Services Without Direct Patient Contact (0.98).
to calculate the 0.61 work RVU for the non-face-to-face component of 99495. Equating CCM to the non-face-to-face component of TCM, CMS assigns a 0.61 work RVU to CCM.

In its proposed rate of reimbursement for CCM, however, CMS does not calculate the PE RVU and the ME RVU for CCM based on the non-face-to-face component of TCM, the next reasonable step forward. If CMS would have taken this step in its proposal, the result would be a PE RVU based on the 2.34 practice expense RVU for 99495, minus the 1.41 practice expense RVU for 99214, resulting in a practice expense RVU of 0.93 for CCM. Using this approach, the ME RVU for CCM would have been 0.09 (0.19 malpractice expense RVU for 99495 less the 0.1 malpractice expense RVU for 99214).

As a result, the combined practice and malpractice expense RVU for CCM would have been 1.02, if CMS had applied the same logic it used to calculate the work RVU for CCM. This would have resulted in a monthly reimbursement for CCM of $58.39 per eligible beneficiary, based on the following calculation: [0.61 wRVU + 1.02 PE/MP RVU] x $35.8228 conversion factor = $58.39. Notably, this rate is consistent with the CMS-approved per-beneficiary-per-month rate of $58.87 for Medicaid primary care practice health home services in the State of Missouri. In addition, other states’ approved health home programs have lower reimbursement, but the scope of services are considerably constrained in comparison to the Missouri program or Medicare CCM.

Based on the above, TIA believes that CMS should strive for consistency in its approach to RVU calculations, particularly for Medicare services having much in common with existing approaches used in Medicaid. We therefore urge CMS to adopt a PE RVU of 0.93 and a ME RVU of 0.09.

D. **CMS Should Include CCM Services for Defined Rural Health Clinic and Federally Qualified Health Center Services**

Currently, CMS utilizes CPT 99495 and 99496 to provide Medicare PFS payment for transitional care management (TCM). Subsequent to these codes being established, CMS issued Transmittal 173 in November of 2013, updating Chapter 13 of CMS Pub. 100-2, *Medicare Benefit Policy Manual*, to allow Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) to enjoy TCM benefits. As a result, CMS reimburses RHCs or FQHCs that provide TCM to eligible beneficiaries, using the applicable RHC or FQHC comprehensive rate. However, as proposed by CMS, CCM would not include a face-to-face encounter as mandatory.

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(unlike TCM). CMS would only reimburse a RHC or FQHC using the comprehensive rate for beneficiary visits for covered services,\(^\text{17}\) with a visit defined as face-to-face encounter.\(^\text{18}\) As a result, CCM would not be a reimbursable service for RHCs or FQHCs at the applicable comprehensive rate.

TIA notes that the definition of both a RHC\(^\text{19}\) and a FQHC\(^\text{20}\) do not include the face-to-face obligation, and only require that RHC and FQHC services to be “furnished to an individual as an outpatient of” the RHC or FQHC. Legally, we believe that CMS has the authority to increase the definition of RHC and FQHC services to include CCM in the Code of Federal Regulations, despite CCM not necessarily involving a face-to-face encounter. From a policy perspective, TIA supports this approach because RHCs and FQHCs serve as primary care providers for patient populations with a large percentage of beneficiaries eligible for CCM; therefore CMS would further public policy goals by encouraging and enabling providers to develop necessary capabilities to provide CCM rather than leaving Medicare beneficiaries in many rural and underprivileged communities underserved.

Based on the above, TIA supports the amendment of 42 CFR 405.2463(a)(1) as follows:

(a) Visit—(1) General. (i) For rural health clinics, a visit is—

(A) A face-to-face encounter between a clinic or center patient and a physician, physician assistant, nurse practitioner, nurse midwife, visiting nurse, clinical psychologist, or clinical social worker; or

(B) Chronic care management services.

(ii) For FQHCs, a visit is—

(A) A face-to-face encounter or chronic care management services, as described in paragraph (a)(1)(i) of this section; or

(B) A face-to-face encounter between a patient and a qualified provider of medical nutrition therapy services as defined in part 410, subpart G of this chapter; or a qualified provider of outpatient diabetes self-management training services as defined in part 410, subpart H of this chapter.

Furthermore, after the publication of the 2015 Medicare Physician Fee Schedule Final Rule, CMS should make relevant changes to the Medicare Benefit Policy Manual to

\(^{17}\) 42 CFR 405.2462.

\(^{18}\) 42 CFR 405.2463.

\(^{19}\) 42 USC 1395(x)(aa)(1).

\(^{20}\) 42 USC 1395(x)(aa)(3).
define the specific requirements for RHCs and FQHCs to provide CCM, similar to those revisions contained in Transmittal 173 with regard to TCM.

1. **In the Alternative, CMS Should Clarify That CCM Furnished by a Rural Health Clinic or Federally Qualified Health Center Constitutes a Non-Rural Health Clinic or Non-Federally Qualified Health Center Service for Which the Rural Health Clinic or Federally Qualified Health Center May Bill Separately.**

   Should CMS choose not to include CCM as a reimbursable service for RHCs or FQHCs at its applicable all-inclusive rate, CMS should clarify that CCM furnished by an RHC or FQHC may be reimbursed as a non-RHC/FQHC service. Non-RHC/FQHC services are addressed in Section 60 of Chapter 13 of the *Medicare Benefit Policy Manual*. Specifically, Section 60.1 includes a list of Medicare covered services that are not included in the RHC or FQHC benefit for which an RHC or FQHC may bill separately to the appropriate Medicare Administrative Contractor under the payment rules that apply to that service.

   That list includes (1) the technical component of an RHC or FQHC service, (2) laboratory services, (3) durable medical equipment, (4) ambulance services, (5) prosthetic devices, (6) body braces, (7) practitioner services at certain other Medicare facilities, (8) telehealth distant-site services, and (9) hospice services. While this list is described as non-exclusive, the fact CCM is not specifically identified as a service for which an RHC or FQHC may receive payment may discourage these providers from furnishing CCM.

2. **CMS Should Permit CCM and Transitional Care Management Furnished by a Rural Health Center or Federally Qualified Health Center to be Furnished “Incident to” Under General Supervision.**

   CMS proposes to amend 42 CFR 410.26(b)(5) to state “[s]ervices and supplies incident to [TCM] and [CCM] services can be furnished under general supervision of the physician (or other practitioner)” when these services or supplies are provided by clinical staff.” CMS also proposes to amend the RHC/FQHC “incident to” regulations (45 CFR 405.2413 and 405.2415), to eliminate the requirement that the individual providing the “incident to” service must be an employee of the clinic. However, CMS does not propose to amend these regulations to allow for TCM or CCM to be furnished under general supervision.

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21 Proposed PFS at 40366-7.
22 Id at 40367.
The same reasoning CMS followed in proposing revisions to 42 CFR 410.26(b)(5) applies to the RHC/FQHC “incident to” regulations. Therefore, in addition to eliminating the employment requirement, CMS should revise its proposed revisions to 42 CFR 405.2413(a)(5) and 405.2415(a)(5) to incorporate the same language as CMS proposes to add to 42 CFR 410.26(b)(5):

405.2413(a)(5) Furnished under the direct supervision of a physician, except services and supplies furnished incident to transitional care management and chronic care management services, can be furnished under general supervision of a physician when these services or supplies are furnished by clinical staff.

405.2415(a)(5) Furnished under the direct supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, except services and supplies furnished incident to transitional care management and chronic care management services, can be furnished under general supervision of a nurse practitioner, physician assistant, or certified nurse-midwife when these services or supplies are furnished by clinical staff.

E. CMS Should Provide a Model Agreement for Beneficiaries to Consent to the Provision of CCM

In a number of instances, HHS has provided forms or model agreements to assist health care providers in complying with complex regulatory requirements. For example, HHS’ Office of Civil Rights has promulgated sample Business Associate Agreement provisions and model Notices of Privacy Practices.

Similarly, CMS has provided a form for the Advanced Beneficiary Notice of Noncoverage (Form CMS-R-131) and several forms for participants in the Medicare Shared Savings Program (MSSP). These include, for example, a Notice to Patient that the beneficiary’s physician is participating in an MSSP Accountable Care Organization (ACO) and affording the beneficiary the opportunity to opt out of data sharing between CMS and the ACO.

These forms and model agreements facilitate compliance with regulatory requirements, which in turn helps to assure that beneficiaries receive the information and services that the applicable regulations are intended to facilitate. The forms and model agreements also reduce the cost of compliance for health care providers, allowing scarce resources to be used for care rather than expended on administrative overhead.

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24 See www.hhs.gov/ocr/privacy/hipaa/modelnotices.html.
We propose that CMS publish a model agreement for beneficiaries to consent to the provision of CCM. This model agreement would assure that beneficiaries are notified of the availability of CCM, the beneficiary’s rights with respect to CCM, and the practitioner’s obligations associated with such services.

The regulatory requirement to provide notice and obtain written consent as a condition for billing for CCM is unlike other billing rules to which practitioners now must adhere to. Uncertainty regarding compliance with this requirement is likely to discourage some practitioners from providing this service. CMS can eliminate this uncertainty and therefore improve the likelihood CCM will be available to qualifying beneficiaries by publishing definitive guidance in the form of a model consent agreement.

**F. CMS Should Create an Additional Separate Code for CCM Incorporating Electronic Remote Patient Monitoring to Which a Higher Practice Expense RVU Is Assigned.**

To be efficient and effective, chronic care management for certain conditions (e.g., hypertension, diabetes, COPD, renal failure, asthma, heart failure, Parkinson’s disease, Alzheimer’s disease, and obesity) should incorporate electronic remote patient monitoring. Such monitoring consists of electronically transmitted biometric data that originates with the patient (referred to as “patient generated health data” or “PGHD”) and transmits automatically, without patient reporting, to designated providers.

Advances in electronic remote patient monitoring technology allow for biometric data to be transmitted and evaluated in real time by clinicians who can respond immediately with clinically-guided support such as changes in treatment, medications, and lifestyle. The biometric data can be automatically downloaded and stored in providers’ electronic health record where it can be used to identify trends and to modify the care plan, if necessary.

The real-time information and response achieved with electronic remote patient monitoring enables early identification of changes in a patient’s condition and early intervention to address the change before it develops into an acute episode. CMS should encourage providers to use electronic remote patient monitoring by establishing a separate code for “CMM with electronic remote patient monitoring” that compensates providers for the added practice expense associated with acquiring, maintaining, and upgrading the technology for electronic remote patient monitoring and installing and educating the patient and caregivers regarding the use of the technology.

In finalizing CMS’ proposed new Healthcare Common Procedure Coding System (HCPCS) code, we strongly recommend that CMS make a conforming modification regarding CPT code 99091, collection and interpretation of physiologic data, for a 30-day period. This is the most relevant remote monitoring code that has a Medicare RVU greater than 0.00. After the 99091 code was created, CMS unilaterally decided to require that it be “bundled” with other “evaluation and management” services to the Medicare patient. Although coding and rate setting for remote patient monitoring services may ultimately warrant a more comprehensive arrangement, a responsible and realistic step forward at this time would be that the final rulemaking explicitly recognize that 99091 can be used in conjunction with GXXX1.
IV. Conclusion

We respectfully request that CMS consider the above comments in its continued improvements to the Medicare program. TIA members look forward to the release of the final draft of these rules, and to working with CMS.

Respectfully submitted,

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