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Dear Senators,

The National Rural Health Association (NRHA) appreciates the opportunity to discuss the impact of chronic disease in rural America in response to the Senate Finance Committee Bipartisan Chronic Care Working Group Policy Options Document from December 2015 requesting input from stakeholders. We applaud the committee for undertaking this difficult and complex task.

Access to quality, affordable health care is essential for the 62 million Americans living in rural and remote communities. Rural Americans are more likely to be older, sicker and poorer then their urban counterparts. Specifically, they are more likely to suffer with a chronic disease that requires monitoring and follow up care, making convenient, local access to care necessary to ensuring patient compliance with the services that are necessary to reduce the overall cost of care and improve the patients' outcomes and quality of life. Yet, many rural Americans live in areas with limited health care resources, restricting their available options for care, including primary care. Furthermore, the lack of local accessible options for care reduce the likelihood of proper management of these conditions, leading to not only reduced quality of life, but at an overall greater cost to the Medicare program.

Rural health care delivery is challenging. Workforce shortages, older and poorer patient populations, geographic barriers, low patient volumes and high uninsured and under-insured populations are just a few of the barriers. Rural physicians and hospitals work around many of these barriers to provide high quality personalized care to their communities. Congress has address some of the payment related barriers by creating specific payment structures for certain rural providers to better address the unique patient populations and structural challenges faced by these small rural practices.

The National Rural Health Association (NRHA), a non-profit membership organization with more than 21,000 members in rural America. NRHA membership is made up of a diverse collection of individuals and organizations, all of whom share the common bond of ensuring all rural communities have access to quality, affordable health care.

Rural Americans are on average older than their urban counterparts and therefore, are disproportionately represented in the Medicare population. Though rural Americans make up around approximately 18 percent of the national population, in 2010, 23 percent of Medicare beneficiaries resided in rural areas.[1] Failing to consider rural populations unique needs would hinder the committee's attempts to deal with the issue of chronic disease.

While we understand why so many of the policy proposals focused on the Medicare Advantage (MA) and Accountable Care Organization (ACO) programs, we are concerned that this focus with miss the 62 million of Americans that call rural America home. Both of these programs have very low penetration in rural areas because of the very issues that make rural America a unique and challenging environment for providing health care. Similar policy levers in rural America must look at broader policy considerations to account for low patient volumes and ultimately achieve the necessary policy ends.

Rural Americans are less likely to be enrolled in a MA plan (17% vs. 28%). The cause of this disparity is fewer plan choices, higher MA premiums (including far fewer zero premium plans), and high year to year variability in the plan offerings making it a less consistent option for rural seniors.

According to Medicare Shared Savings Data, 93% of all ACOs are located within high or mixed population density regions. While there are rural ACOs that are doing wonderful work in rural areas. ACOs are typically clustered around urban and suburban areas, taking advantage of the extensive options for care coordination with large patient practices surrounded by extensive choices of hospitals and specialty providers.

NRHA supports the development of additional flexibility within the ACO program, including the expanded use of telemedicine and expansion to allow ACOs to work with terminally ill patients. However, we are generally concerned with the desire to expand the use of two sided risk. Rural beneficiaries are already less likely to be in an ACO since rural participation is already limited because of the reduced patient volumes statistically requires greater change to demonstrate improvement coupled with the additional costs associated with low volume.

Reforming healthcare delivery models is the new imperative in healthcare, with new innovations focusing on evidence-based care, outcomes and transparency to deliver high quality and cost effective care. Yet, as our nation's urban areas continue to modernize their delivery models, critical access hospitals (CAHs) that serve patients with multiple chronic conditions in our rural communities are increasingly being left behind. Rural Americans face unique challenges that create disparities in healthcare not found in urban areas. Rural residents, on average, are older, have lower incomes, report fair to poor health status, and suffer from higher rates of chronic illness and obesity. Additionally, small rural, facilities face challenges in implementing quality improvement efforts including limited resources, small staffs, and inadequate information technology resources. Independent rural practices often do not have the devoted resources and technology to engage in care management, which is necessary to coordinate care and manage population health.

[1] "Chart 2-5: Characteristics of the Medicare population, 2010", *A Data Book: Health care spending and the Medicare Program* . MedPAC. June 2014.
http://medpac.gov/documents/publications/jun14databookentirereport.pdf

Under the current system, and with razor thin margins, there is no advantage for these small remote facilities to join in the journey to population health. This is evident by the very few ACOs that operate exclusively in non-metropolitan counties. To improve care and increase coordination for these vulnerable populations, CAHs need to have mechanisms that are different from existing models that will bring them into the fold. In the absence of such mechanisms, we risk creating a two-tiered system: one based on quality and accountability in urban and suburban settings, and another based on volume leading toward poor health outcomes in rural, less advantaged areas.

To address this situation, we need a new model that focuses on rural priority areas and seeks to transform financial and clinical models at CAHs. The ideal solution is to create a unique value-based purchasing (VBP) program with CAHs across the U.S. and garner evidence of the program's viability on a broad scale before nationwide implementation. The goal is to demonstrably improve quality and the patient's experience of care while simultaneously reducing inpatient and outpatient costs in rural communities.

To accomplish this objective, the model would implement payment incentives tied to performance on: evidence-based care, mortality, safety, patient experience, care coordination and spending. Through this program, CAHs would earn up to 2 percent bonus on inpatient and outpatient services if they meet quality, patient experience and efficiency targets during the first and second years of the program. If, after three years, it can be demonstrated that the group of CAHs as a whole reduced total Medicare spending for the population they service, then a share of those savings would generate a pool for incentive payments to be distributed back based on related performance. If no statistically valid savings are shown, then no incentive payments would be paid out. This sets up a group shared savings pool that overcomes the statistical reliability challenges associated with calculating savings at the individual CAH level because of the low volume of cases.

As remote providers, CAHs serve patients with myriad conditions, including many of CMS' priority conditions. These will be key improvement areas for the program. A preliminary measure set would bring focus to these conditions including: heart failure, acute myocardial infarction, diabetes, stroke, behavioral health, obesity, and COPD. Using this standardized set of metrics, the new VBP program will help CAHs demonstrate value by lowering inpatient admissions, readmissions and emergency department use as well as post-acute care. This in turn will reduce CMS spending while improving the quality of care delivered in rural communities.

The additional funding from the incentive pool would provide these small facilities with the incentive to begin the journey to population health despite their cost-based payment system without asserting undue risk that could close their doors. The program would create a sustainable model that could bring ACO-like incentives to improve health and healthcare at a lower cost to roughly 19 percent of the country's population.

While this policy is broad, the impact on chronic care management is clear. Chronic disease is a substantial in rural communities, representing a large cost to the health care system. The ability of rural facilities to impact population health will allow for a direct impact on chronic disease in rural America.

NRHA is generally very supportive of the idea of developing quality measures for chronic conditions. We have reservations regarding measures at the community level that are a function of risk behaviors because those risk behaviors may only be reflective of the county. Such

measures could be useful when utilized in the context of a broad population health solution. Outside that context we are concern that rural areas within a county may actually have populations that exhibit higher risk behaviors and therefore not be adequately captured by a county level measure. Any risk score, however, must take into account risk behaviors and social determinants in order to better reflect the population being managed. It is concerning that HCC scoring does not consider behavioral risks and social determinants have an impact on the complexity of chronic care and the subsequent management.

As you know, dually eligible Medicare and Medicaid beneficiaries are one of the most vulnerable and costly populations. Rural beneficiaries are more likely to be dual eligible than urban beneficiaries (17.9% rural vs. 15.8% urban; $p<.0001$).[2] However, a focus on primary as opposed to specialty care in rural settings, results in rural beneficiaries having a lower median total expenses than urban beneficiaries ($3,002 rural vs. $3,439 urban; $p<.001$).[2] This population of poor beneficiaries are more likely to be sicker than non dual eligible populations, and more importantly is likely to have multiple chronic conditions.

Rural Americans are also sicker than their urban counterparts. For example, rural Americans experienced a greater incidence of diabetes than their urban counterparts (9.0 % non-metro vs. 7.0 % metro). [3] Additionally, rural Americans are more likely to experience adverse events as a result of their disease state. 18% of non-metro population experience limitations of activity caused by chronic health conditions vs. 13% of the metro population[4]. More concerning, the non-metro population experiences higher mortality rates from ischemic heart disease (non-metro 201/100,000 population vs. metro 181/100,000 population) and COPD (non-metro 81/100,000 vs. metro 63/100,000).[3]

Partially, this greater incidence and severity steps from the fact that rural Americans are more likely to engage in behavior that increases the chance of chronic disease such as smoking (For individuals 18 and older: 27% smoking rate in non-metro areas vs. 18% metro). Rural Americans are additionally much more likely to be obese than Americans living in urban areas (For individuals 18 and older: non-metro 34% of men and 37% of women vs. metro 28% of men and 30% of women).[3]

Rural Americans also face health care challenges that make them less likely to receive preventive care and screenings which could catch prevent or catch chronic disease early. Ninety-seven percent of the nation's 2,041 rural counties are Health Professional Shortage Areas. And when rural patients require more advanced care, more than 40% of rural patients have to travel 20+ miles to receive specialty care compared to 3% of metropolitan patients. Six hundred and forty counties across the country are without quick access to an acute-care hospital, a statistic likely to become as 66 hospitals have closed since 2010 with more on the brink of closure. Without local access to care rural Americans are less likely to receive preventive care, early screening, or receive sufficient follow-up care.

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[2] Bennett, K. J. et al. Characteristics, Utilization Patterns, and Expenditures of Rural Dual Eligible Medicare Beneficiaries. November 2014. http://rhr.sph.sc.edu/report/%2813-1%29RuralDualEligible_MedicareBeneficiaries.pdf

[3] Hale, N., Bennett, K.J., and Probst, J.C. "Diabetes Care and Outcomes: Disparities Across Rural America" J Community Health. 2010;35(4):365-374. http://www.medscape.com/viewarticle/729003_3

[4] Meit, M. et al. *The 2014 Update of the Rural-Urban Chartbook*. October 2014. https://ruralhealth.und.edu/projects/health-reform-policy-research-center/pdf/2014-rural-urban-chartbook-update.pdf

We are supportive generally of expanding the Independence At Home model of care. This program allows for the delivery of care, when appropriate, in the beneficiaries home. However, in order for this program to work for rural beneficiaries, it is important the program that the program take into account the fact that care delivery in rural America involves lower patient volumes and broad geographic distances. Therefore, the programs expansion into rural America must take this into account and make sufficient changes to allow for success. For example, allowing greater use of technology for visits in place of in person encounters and higher compensations when providers must travel greater distances to make the program cost effective for these providers to participate.

NRHA is supportive of greater use of Center for Medicare and Medicaid Innovation (CMMI) demonstration projects. Ultimately, we do not think the use of notice and comment rulemaking is necessary and may instead slow the process and reduce the use of CMMI demo authority.

Changes to increase the use of CCM services

We are supportive of encouraging the use of the chronic care management services. We believe that providers who are able to waive copays when they feel it is in the best interest of patient care, are appropriate and may enhance the likelihood of some beneficiaries getting the care they need. The removal of barriers to make the chronic care management service easier to utilize and bill is an improvement.

Eliminate the Scope of Service Requirement For Use of a Certified EHR

NRHA supports the elimination of the scope of service requirement for use of a certified EHR. Without a doubt, the scope of service requirement for use of a certified EHR has proven the single greatest obstacle to CCM adoption. While providers understand and appreciate the need for an electronic care plan to facilitate CCM, its relationship to the EHR scope of service requirement has caused significant confusion, to the point many providers have abandoned their early excitement regarding CCM.

Take, for example, an ACO whose membership includes several small physician practices. The ACO members desire to create a centralized care management program, making properly supervised care management staff available to multiple practices that otherwise could not offer CCM to their patients. The program's core components include the following: (1) the ACO hires care management staff to be supervised by the ACO's medical director; (2) the ACO implements a technology solution that enables practices to generate and share an electronic care plan for those patients who consent to receive CCM; (3) the electronic care plan becomes the vehicle for communication between the practice and the ACO's centralized care managers; and (4) the practice bills for CCM, paying the ACO for the care managers' services from the reimbursement revenue.

We are aware of hundreds of organizations – not just ACOs – that have explored such an arrangement, with minor variations. Each has grappled with the question of how to reconcile the arrangement with the certified EHR scope of service requirement. For example:

- Does the electronic care plan have to be interoperable with each practice's EHR?

- Does any change in the patient's demographic information, problem list, medications, or allergies as recorded in the EHR have to be updated immediately in the electronic care plan?

- When the electronic care plan is shared among providers, does the EHR-generated summary care record also have to be shared?

- How will documentation of communications with home and community-based providers be captured in the practice's EHR?

The lack of definitive answers to these questions has resulted in most organizations moth-balling their plans for care management programs.

CMS can greatly simplify the scope of service requirements – and thus greatly expand the number of Medicare beneficiaries receiving CCM services - while still ensuring an appropriate level of care coordination – by eliminating the certified EHR requirements and re-defining the rules regarding the electronic care plan as follow:

1. The plan must incorporate the patient's up-to-date demographic information, problem list, medication list, and allergies;

2. The plan must be made available electronically to members of the patient's care team; and

3. The plan must include documentation of the patient's consent to receive CCM services and communications with home and community-based providers regarding the patient's specific needs.

The billing provider should be responsible for maintaining documentation that the patient has been offered a copy of the care plan in electronic or paper format, with this requirement being satisfied if the current version of the care plan is available through the billing provider's patient portal.

Each of the substantive reasons CMS cited in imposing the EHR scope of service requirement still would be met by refining and clarifying the electronic care plan requirement. Altering the scope of service requirements in this manner will drive providers to seek innovative solutions for information-sharing in a secure and timely manner, rather than abandoning opportunities due to unnecessary regulatory restrictions. As EHR systems mature and interoperability becomes commonplace, CMS may re-visit this scope of service requirement to ensure CCM is being furnished in an appropriate manner given technological advancements.

Revise CCM Eligibility Requirements By Eliminating the Reference To the Acuity Level Of the Beneficiary's Chronic Conditions

CMS' CCM eligibility requirements limit the availability of the service to those Medicare beneficiaries with two or more chronic conditions which "place the patient at significant risk of death, exacerbation/decompensation or functional decline." To determine whether a beneficiary

qualifies for CCM, a practitioner must make a subjective determination regarding the acuity level of the beneficiary's chronic conditions.

CMS has not suggested any criteria – nor do any objective criteria exist – by which to categorize an individual's chronic condition as a significant risk versus a moderate or low risk of death, exacerbation/decompensation or functional decline. The lack of such criteria and the associated risk of providing services for a beneficiary who later may be deemed ineligible by an administrative contractor, an auditor, or an investigator is a frequently cited reason for providers not making the necessary investments to provide CCM for their patients.

Additionally, imposing this risk requirement goes against the very reason CMS now proposes to pay for CCM. For many chronic conditions, the significant risk to the beneficiary's health is associated with not properly managing the condition. Therefore, by receiving care management, and thus reducing the risk associated with the chronic condition, a beneficiary would become ineligible for future care management services. The beneficiary would again be eligible for CCM at the point he or she was again at risk due to the lack of proper management. This vicious cycle certainly is not what CMS intended, but it is the result of imposing the risk requirement

Instead of requiring some undefined evidence of significant risk as a condition of receiving CCM, CMS should instead adopt eligibility criteria similar to the criteria for the Medicaid health home benefit. Section 2703 of The Affordable Care Act created an optional Medicaid State Plan benefit for states to establish health homes to coordinate care for Medicaid beneficiaries with chronic conditions.

Specifically, the statutory language provides that health home services may be made available to Medicare beneficiaries who (1) have two or more chronic conditions; (2) have one chronic condition and are at risk for a second; or (3) have one serious and persistent mental health condition. Section 2703 lists specific qualifying chronic conditions and vests the Secretary with the authority to expand the list as he or she determines appropriate.

Similarly, CMS should define eligibility for CCM based on a beneficiary's diagnosis with specific chronic conditions as opposed to a subjective determination of the level of risk associated with a condition. Specifically, CMS could reference those conditions and disabilities tracked through the CMS *Chronic Condition Warehouse.*

Provide a Model CCM Consent Form

The regulatory requirement to provide notice and obtain written consent as a condition for billing for CCM is unlike other billing rules to which providers now must adhere. Uncertainty regarding compliance with this requirement has proven to discourage some providers from furnishing 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.

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 (at www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/contractprov.html) and model Notices of Privacy Practices (at www.hhs.gov/ocr/privacy/hipaa/modelnotices.html).

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.

CMS should 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.

Clarification On Who Qualifies as "Clinical Staff" For Purposes of Providing Non-Face-To-Face Care Management Services

Another ambiguity in the CCM and TCM billing rules CMS should resolve is who qualifies as "clinical staff" for purposes of providing non-face-to-face care management services that count toward the twenty-minute requirement. Presumably, any individual licensed by the state to practice a health care professional would qualify. However, CMS has not clarified whether a non-licensed individual, such as a medical assistant, would be considered clinical or clerical staff.

In the 2015 Final Rule (specifically, Table 31, *CY 2015 Final Interim Codes With Direct Input PE Recommendations Accepted With Refinements*), CMS indicated non-face-to-face care management services would be performed by an "RN/LPN/MTA." 79 Fed. Reg. 67,711 (Nov. 11, 2014). CMS also has referenced "MTAs", or Medical Technical Assistants, in the context of computerized physician order entry for under the Medicare and Medicaid EHR Incentive Programs. In the context of those programs, CMS requires that only "credentialed medical assistants" (in addition to licensed health professionals) may enter medication, radiology, and laboratory orders into the electronic health record to have such entry count toward meeting the meaningful use thresholds.

Based on this, many providers believed only licensed or credentialed individuals qualified as "clinical staff." And, as most medical assistants are not presently credentialed, this has become another barrier to adoption of CCM and TCM programs.

Now in the Proposed Rule, it appears CMS is interpreting the term more broadly:

For purposes of meeting the minimum 20-minute requirement, the RHC or FQHC could count the time of only one practitioner or auxiliary staff (*for example, a nurse, medical assistant, or other individual working under the supervision of a RHC or FQHC physician or other practitioner*) at a time, and could not count overlapping intervals such as when two or more RHC or FQHC practitioners are meeting about the patient.

80 Fed. Reg. 41,794-95 (July 15, 2015) (emphasis added).
To eliminate any ambiguity, and to ensure care management services become more widely available, CMS should clarify that no specific licensure or certification is required for an individual to provide non-face-to-face care management services. Instead, it is the responsibility of the physician or non-physician practitioner providing general supervision to ensure the individual (1) is qualified by training and/or experience to furnish the specific service, and (2) satisfies any and all applicable state law requirements for an individual furnishing such service.

Clarification On CCM Documentation Requirements

Many providers have expressed concerns regarding what constitutes sufficient documentation of non-face-to-face care management services. While this subject may not be the appropriate subject of rulemaking, CMS should provide clear guidance on this subject. Specifically, CMS should address how the amount of time spent providing services should be reported, *i.e.*, whether start and stop time are required.

Again, many providers have indicated that the lack of a reliable method to capture work time other than self-reporting by the individual furnishing the service is yet another obstacle to establishing a CCM program. Thus, CMS should clarify that self-reported time (with start and stop times not required), accompanied by the name of the staff member and a brief description of the service provided is sufficient documentation of non-face-to-face care management services.

Clarification On Remote Patient Monitoring

With respect to remote patient monitoring (RPM), CMS previously has clarified that "these activities would count towards the minimum 20 minutes of qualifying care per month that are required to bill CPT 99490," provided it is not the only work done for a patient receiving CCM.[5] CMS now should specify that time spent monitoring patient-generated health data to identify anomalies signaling the need for intervention (*e.g.*, sudden weight gain by a beneficiary suffering from congestive heart failure) may be counted even if the staff member is monitoring other beneficiaries simultaneously.

In such circumstances, the staff member should appropriately allocate time among multiple beneficiaries. For example, if the staff member spent one hour each week reviewing data for ten beneficiaries, six minutes would be reported for each beneficiary.

Assign a Practice Expense RVU Of 0.93 and a Malpractice Expense RVU Of 0.09 To 99490

In establishing the reimbursement for 99490, CMS assigned a practice expense RVU of 0.57 and a malpractice expense RVU of 0.04. With regard to the practice expense RVU, the only input CMS addressed directly is 20 minutes of clinical time, based on the *minimum* amount of time required to be spent on non-face-to-face care management services in order to bill for CCM. This clinical time accounts for 0.42 of the 0.57 practice expense RVU.

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[5] MLN Matters No. SE1516, *Chronic Care Management (CCM) Services Frequently Asked Questions (FAQ)*, at 4, available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1516.pdf

By restricting the labor costs to 20 minutes of clinical time, CMS failed to account for any time spent preparing to deliver care management services (*e.g.*, compilation and review of documentation), documenting the provision of those services, or updating a beneficiary's care plan, none of which presumably counts toward the 20-minute minimum requirement. Nor does CMS account for the cost involved in having a clinician available on a 24/7 basis to address beneficiary's urgent chronic care needs.

The combined PE/MP RVU of 0.61 is significantly lower than the combined PE/MP RVUs assigned to similar services, such as the following services identified by CMS as those for which a practitioner cannot bill during the same time period for which the practitioner is billing CCM:

Service	**Combined PE/MP RVU**
G0181 Home Healthcare Oversight	1.28
G0182 Hospice Care Plan Oversight	1.30
99339 Care Plan Oversight Services	0.94
99358 Prolonged Services Without Direct Patient Contact	0.98

In assigning the work RVU for 99490, CMS drew a tight analogy between CCM and transitional care management. CMS determined the 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, subtracted 1.5 (work RVU for 99214) from 2.11 (work RVU for 99495) 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 assigned a 0.61 work RVU to CCM.

In calculating its rate of reimbursement for CCM, however, CMS veered away from the next logical step, which would have been to calculate the practice expense RVU and the malpractice RVU for CCM based on the non-face-to-face component of TCM. Had CMS been consistent in its reasoning, it would have assigned a practice expense RVU based on the 2.34 practice expense RVU for 99495 less the 1.41 practice expense RVU for 99214, resulting in a practice expense RVU of 0.93 for CCM. Again, using the same logic, the malpractice expense 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 $58.57 per eligible beneficiary, based on the following calculation: [0.61 wRVU + 1.02 PE/MP RVU] x $35.9335 current conversion factor = $58.57.

PYA urges CMS to increase the practice expense RVU from 0.57 to 0.93 and the malpractice expense RVU from 0.04 to 0.09, for a combined PE/MP RVU of 1.02. The resulting $14.74

increase in reimbursement for 99490 would more fairly compensate providers for their investment in CCM, thus making this critical service more broadly available to eligible beneficiaries.

Provide Reimbursement for CPT 99487, Complex Chronic Care Management Services

Experience counsels that some beneficiaries with chronic conditions will experience periods of time during which their need for care management services will be significantly greater than usual. For example, the loss of a spouse or change in living conditions may result in a rapid decline, requiring the beneficiary's care manager to communicate with the beneficiary and his or her caregivers and other providers more frequently.

To fairly compensate providers for the additional resources required to properly support a beneficiary in such circumstances, CMS should provide reimbursement for complex chronic care management services, CPT 99487. CCCM is identical to CCM, except it requires a minimum of sixty minutes of non-face-to-face care management services, as compared to the twenty minute-minimum for CCM. Given the alternative to more aggressive care management services, including costly emergency room visits and hospitalizations, the additional reimbursement for these services is a wise investment.

Eliminate the Co-Insurance Requirement For CCM

Those providers that have explored providing CCM to eligible patients have reported to PYA that many patients have refused to consent to CCM due to the co-insurance requirement. CMS previously has stated it lacks the authority to waive this requirement because CCM is not within the statutory definition of "preventive services" for which Medicare provides first-dollar coverage.

CMS, however, has the authority under 42 U.S.C. 1395x(ddd) to designate a service as an "additional preventive service" through the national coverage determination process if such service has been "recommended with a grade of A or B by the United States Preventive Services Task Force." Upon such designation, Medicare covers 100 percent of the cost for that service pursuant to 42 U.S.C. 1395l(a)(1)(Y).

PYA urges CMS to work with the U.S. Preventive Services Task Force to have that entity recommend CCM with a grade A or B. CCM qualifies for such designation for the very reasons CMS made the decision to provide reimbursement for this service. While the Task Force's processes must be respected, any delay in such designation and CMS' subsequent publication of an NCD will limit widespread adoption of CCM.

Improved Payment for the Professional Work of Care Management Services

CMS has recognized the need to adequately compensate physicians and non-physician practitioners for the work they perform in managing beneficiaries with chronic conditions beyond face-to-face visits and supervision of clinical staff providing non-face-to-face care management services. Now CMS should move quickly in providing adequate reimbursement for these services, as such payment provides a bridge for providers from volume- to value-based reimbursement.

Specifically, CMS could make relatively minor modifications to the current scope of service for care plan oversight (CPO) to allow for such reimbursement. The new CPO would be limited to patients who have consented to receive CCM, as opposed to home health and hospice patients. Otherwise, the core professional services would remain the same:

- Reviewing charts, reports and treatment plans
- Reviewing diagnostic studies if the review is not part of an E/M service
- Talking on the phone with other health care professionals who are not employees of the practice and are involved in the patient's care
- Conducting team conferences
- Discussing drug treatment and interactions (not routine prescription renewals) with a pharmacist
- Coordinating care if physician or nonphysician practitioner time is required
- Making and implementing changes to the treatment plan.

Payment For CCM To RHCs and FQHCs

CMS should revise the "incident to" regulations applicable to RHCs and FQHCs for purposes of CCM. In 2015, CMS amended 42 CFR 410.26(b)(5) to state in relevant part "[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."

The same reasoning CMS followed in revising 42 CFR 410.26(b)(5) applies to the RHC/FQHC "incident to" regulations. Therefore, CMS should revise 42 CFR 405.2413(a)(5) and 405.2415(a)(5) to incorporate the same language as CMS added to 42 CFR 410.26(b)(5) in 2015:

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.*

CMS Should Amend 42 CFR 410.78(a) To Reflect Technological Advances Since the Regulation's Promulgation Fifteen Years Ago

Section 1834(m) was added to the Social Security Act by Section 223 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). That statutory provision states in relevant part (emphasis added):

(m) Payment for telehealth services.

(1) In general.—The Secretary shall pay for telehealth services that are furnished via a ***telecommunications system*** by a physician (as defined in section 1861(r)) or a practitioner (described in section 1842(b)(18)(C)) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary. For purposes of the preceding sentence, in the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, ***the term "telecommunications system" includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.***

The term "telecommunications system" is not otherwise defined in Section 1834(m) or any other provision in the Act.

In the 2001 Medicare Physician Fee Schedule Final Rule, CMS promulgated 42 CFR 410.78, the regulation that establishes the billing rules for telehealth services. CMS offered the following explanation of the relevant regulatory provision in the regulatory preamble (66 Fed. Reg. 55,281 (Nov. 11, 2000)) (emphasis added):

In this final rule, we are specifying at § 410.78 that, except for the use of store and forward technology in the demonstration programs conducted in Alaska or Hawaii, an interactive telecommunications system must be used and the medical examination of the patient must be at the control of the physician or practitioner at the distant site. ***We are defining interactive telecommunications system as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication*** between the patient and physician or practitioner at the distant site. We are also specifying that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.

A patient need not be present for a Federal telemedicine demonstration program conducted in Alaska or Hawaii. We are specifying that for Federal telemedicine demonstration programs conducted in Alaska or Hawaii, Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system. Additionally, we are specifying that the physician or practitioner at the distant site must be affiliated with the demonstration program.

We are defining asynchronous, store and forward technologies, as the transmission of the patient's medical information from an originating site to the physician or practitioner at the distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines, and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patient's medical condition and adequate for rendering or confirming a diagnosis or treatment plan.

Fifteen years later, 42 CFR 410.78 still includes the same definitions promulgated by CMS in 2000:

42 CFR § 410.78 - Telehealth services.

(a) *Definitions.* For the purposes of this section the following definitions apply:

(1) *Asynchronous store and forward technologies* means the transmission of a patient's medical information from an originating site to the physician or practitioner at the distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines and text messages without visualization of the patient (electronic mail). Photographs visualized by a telecommunications system must be specific to the patient's medical condition and adequate for furnishing or confirming a diagnosis and or treatment plan. Dermatological photographs, for example, a photograph of a skin lesion, may be considered to meet the requirement of a single media format under this provision.

. . . .

(3) ***Interactive telecommunications system*** means multimedia communications equipment that includes, at a minimum, ***audio and video equipment permitting two-way, real-time interactive communication*** between the patient and distant site physician or practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.

. . . .

(b) General rule. Medicare Part B pays for [specified services] ***furnished by an interactive telecommunications system*** if the following conditions are met:

. . . .

Consistent with this regulatory provision, Section 190 in Chapter 12 of the Medicare Claims Processing Manual – the provision in the CMS Manual System that addresses payment for telehealth services – gives the following instruction:

190.1 - Background
(Rev. 1635, Issued: 11-14-08, Effective: 01-01-09, Implementation: 01-05-09)

Section 223 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) - Revision of Medicare Reimbursement for Telehealth Services amended §1834 of the Act to provide for an expansion of Medicare payment for telehealth services.

. . . .

An interactive telecommunications system is required as a condition of payment; however, BIPA does allow the use of asynchronous “store and forward” technology in delivering these services when the originating site is a Federal telemedicine demonstration program in Alaska or Hawaii.

. . . .

190.4 - Conditions of Payment
(Rev. 1, 10-01-03)

1. Technology

For Medicare payment to occur, interactive audio and video telecommunications must be used, permitting real-time communication between the distant site physician or practitioner and the Medicare beneficiary. As a condition of payment, the patient must be present and participating in the telehealth visit.

2. Exception to the interactive telecommunications requirement

In the case of Federal telemedicine demonstration programs conducted in Alaska or Hawaii, Medicare payment is permitted for telemedicine when asynchronous "store and forward technology" in single or multimedia formats is used as a substitute for an interactive telecommunications system. The originating site and distant site practitioner must be included within the definition of the demonstration program.

3. "Store and forward" defined

For purposes of this instruction, "store and forward" means the asynchronous transmission of medical information to be reviewed at a later time by physician or practitioner at the distant site. A patient's medical information may include, but not limited to, video clips, still images, x-rays, MRIs, EKGs and EEGs, laboratory results, audio clips, and text. The physician or practitioner at the distant site reviews the case without the patient being present. Store and forward substitutes for an interactive encounter with the patient present; the patient is not present in real-time.

NOTE: Asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patients' condition and adequate for rendering or confirming a diagnosis and or treatment plan. Dermatological photographs, *e.g.*, a photograph of a skin lesion, may be considered to meet the requirement of a single media format under this instruction.

CMS' fifteen-year-old regulation defining the statutory term "telecommunications system" – a term not specifically defined in the Act - to require the use of "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication" is outdated, given the extraordinary advances in technology over the last decade and a half. The limiting language of 42 CFR 410.78 now precludes Medicare beneficiaries from receiving services as intended by Congress, namely essential healthcare services not otherwise readily accessible absent the use of state-of-the-art telecommunications.

CMS, therefore, should revise 42 CFR 410.78(a) as follows, and make corresponding changes to relevant CMS Manual provisions:

(a) ***Definitions.*** For the purposes of this section the following definitions apply:

(1) *Interactive telecommunications system* means multimedia communications allowing interactive communication between an eligible Medicare beneficiary and distant site physician or practitioner. Telephonic communications, facsimile transmissions, text messaging, and electronic mail systems do not meet the definition of an interactive telecommunications system.

(2) *Distant site* means the site at which the physician or practitioner delivering the service is located at the time the service is provided using an interactive telecommunications system.

(3) *Originating site* means the location of an eligible Medicare beneficiary at the time the service being furnished using an interactive telecommunications system occurs.

Based on this revised regulation, CMS will have the opportunity to expand coverage and establish appropriate reimbursement for telehealth services to include proven interactive communications, including remote patient monitoring.

Hospital Closure Crisis

Rural health care challenges are well known – from accessing health care services to recruiting and retaining health professionals. Rural communities depend on safety net providers such as Critical Access Hospitals, Community Health Centers, Rural Health Clinics and Federally Qualified Health Centers.

But these important rural access points are facing a closure crisis. Sixty-six rural hospitals have closed since 2010; and more are on the brink of closure. Since the start of 2013, more rural hospitals have closed than in the previous 10 years—combined. These closures are a part of a larger trend according to the Cecil G. Sheps Center for Health Services Research at the University of North Carolina, and their numbers show the rate is escalating. Continued cuts in hospital reimbursements have taken their toll, forcing far too many closures and leaving many of our nation's most vulnerable populations without timely access to care.

If Congress allows these rural hospitals on the brink to close, then 700,000 patients would lose direct access to care. Already 640 counties across the country are without quick access to an acute-care hospital. Seventy-seven percent of the nation's 2,041 rural counties are Health Professional Shortage Areas. More than 40 percent of rural patients have to travel 20 or more miles to receive specialty care, compared to 3 percent of metropolitan patients.

A rural hospital closing doesn't just hurt patients; it hurts the rural economy as well. In rural America, the hospital is often one of the largest employers in the community. Health care in rural areas can represent up to 20 percent of the community's employment and income. The average CAH creates 195 jobs and generates $8.4 million in payroll annually. If a rural provider is forced to close their door the community erodes. If we allow the rural hospitals that are on the brink to close: 36,000 direct rural health care jobs will be lost; 50,000 rural community jobs will be lost; and rural economies would take a $10.6 billion loss. When a rural hospital closes, leaving a community without local access to health care, the community quickly begins to die.

Rural Hospitals provide cost-effective primary care. It is 2.5 percent less expensive to provide

identical Medicare services in a rural setting than in an urban or suburban setting. This focus on primary care, as opposed to specialty care, saves Medicare $1.5 billion per year. Quality performance measurements in rural areas are on par if not superior to urban facilities.

NRHA asks members of the Committee to consider the impact of access to care for rural Americans when necessary safety net providers close. While this loss of access to care is devastating to the community as a whole, it is particularly problematic for rural residents with chronic diseases that require ongoing care and monitoring. When local access to care is no longer available, patients are more likely to skip monitoring and follow-up appointment and to wait until the situation become dire, and very expensive, to seek care. This lack of ongoing routine care and monitoring will result in greater need for inpatient hospitalization, longer rehabilitative and post-acute care stays, and in the long run will be more costly to the system overall.

Sixty-six rural hospitals have already closed. NRHA is calling on members of Congress to stabilize the rural hospital closures. Rural health care delivery is challenging. Workforce shortages, older and poorer patient populations, geographic barriers, low patient volumes and high uninsured and under-insured populations are just a few of the barriers. NRHA understands the need for an innovation model for rural hospitals who continue to struggle, while ensuring access to emergency care and outpatient care that meets the needs of their unique rural communities.

NRHA calls on regulatory relief to help the Medicare beneficiaries in rural America. The elimination of the CAH 96 Hour Condition of Payment, the rebase of supervision requirements for outpatient therapy services at CAHs and rural PPS facilities, and modification to the 2-Midnight Rule and RAC audit and appeals process would help relieve burdens placed unfairly on these small, rural hospitals and providers.

NRHA calls for the elimination of the 96 hour Condition of Payment requirement that physicians at CAHs certify, at the time of admission that a Medicare patient will not be at the facility for more than 96 hours. From the creation of the CAH designation until late 2013 an annual average of 96 hour stays allowed CAHs flexibility within the regulatory framework set up for the designation. The new policy of strict enforcement of a per stay 96 hour cap creates unnecessary red-tape and barriers for CAHs throughout rural America; and eliminates important flexibility to allow general surgical services well suited for these high quality local providers.

The 96-hour rule is counter to the clear congressional intent to provide CAHs greater flexibility, evident in the 1999 modification of the 96 hour condition of participation from a hard 96 hour cap to a flexible annual average. The sudden imposition of the condition of payment is unnecessary and limits access to health care in rural areas and disallows rural providers to focus on caring for their patients. This regulation interferes with the best judgment of physicians and other health care providers, placing them in a position where high quality and qualified local providers cannot provide care for their patients. As a result, patients have had to seek care far from home. Additionally, since it is 2.5 percent less expensive to provide identical Medicare services in a rural setting than in an urban or suburban setting, such a transfer results in greater Medicare expenditures. Removing the 96-hour rule condition of payment would allow for rural patients to receive the care they need in their local communities.

Twenty percent of Americans live on the 90% of America that is rural. For these Americans local access to care is essential, but there are substantial barriers and challenges involved in

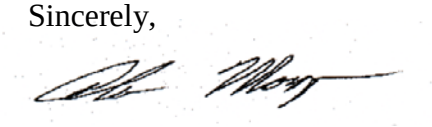
providing this care. The rural payment programs created by Congress address just some of these challenges and help protect the rural health care safety net and provide critical access to health care for rural Americans. Rural physicians and hospitals generate billions of dollars for the local economy. Studies at the National Center for Rural Health Works at Oklahoma State University have found that one full-time rural primary care physician generates about $1.5 million in revenue, and creates or helps create 23 jobs. Rural health care systems make huge economic contributions to their communities. Reducing rates for rural providers will force many facilities to offer reduced services or even close their doors, further reducing access to care for rural Americans and transferring patients to more expensive urban providers. Rural hospital closures also devastate local economies. In the past, a closed hospital has meant as much as a 20 percent loss of revenue in the local rural economy, 4 percent per capita drop in income, and a 2 percent increase in the local unemployment rate.

Medicare payment policies are critical to the ability of our rural health care safety net and the ability for our health care providers to continue to provide quality care to rural Americans. The development of permanent policies that address these issues is vital to the ongoing success and viability of the rural health care safety net.

In the past, members of Congress have looked towards bipartisan rural legislation to address issues in the long-term and provide rural providers with the certainty they need. We encourage the committee to look at the Save Rural Hospitals Act, H.R. 3225, introduced by Reps. Sam Graves (R-MO) and Dave Loebsack (D-IA) as a guide for addressing all these issues in the long-term.

We appreciate your leadership on the issue of chronic disease and look forward to working with you as a stakeholder moving forward. Please feel free to contact Diane Calmus on my Government Affairs staff at (202) 639-0550 or dcalmus@nrharural.org with any questions.

Sincerely,



Alan Morgan
Chief Executive Officer