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September 2, 2014

Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1612-P  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

**Re: CMS-1612-P – Medicare Program; Revisions to the 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 Fed. Reg. 40318 (July 11, 2014)

Dear Administrator Tavenner:

The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

ACS CAN appreciates the opportunity to comment on the proposed rule implementing changes to the calendar year (CY) 2015 Medicare Physician Fee Schedule and other revisions to the Part D program. ACS CAN supports CMS' proposal to add additional services to the telehealth program and encourage the agency to consider further expansion of the program to cover palliative care services. We applaud CMS' recognition of the importance of chronic care management and encourage CMS to evaluate the valuation and requirements of the Chronic Care Management code to ensure beneficiaries are receiving care management services. Finally, we commend CMS' for its proposal to include anesthesia services as part of the screening colonoscopy, but urge the agency to also designate screening colonoscopies that result in polyp removal or biopsy as a preventive service just as the Department of Health and Human Services determined for the health insurance marketplace plans.

## **II. Provisions of the Proposed Rule for PFS**

### **A. Resource-Based Practice Expense (PE) Relative Value Units (RVU)**

#### *4. Using OPPS and ASC Rates in Developing PE RVUs*

In the preamble, CMS expressed concern with the growing trend of hospital acquisition of physician offices and subsequent treatment of these entities as off-campus provider-based outpatient departments. 79 Fed. Reg. at 40333-34. CMS proposes to begin collecting data on the type and frequency of services furnished in off-campus provider-based departments beginning in 2015. CMS proposes to requiring hospitals and physicians to report a modifier for those services furnished in an off-campus provider-based department on both hospital and physician claims.

ACS CAN supports CMS' proposed policy. As noted in the preamble, there has been a significant increase in the number of physician group practices that have been acquired by hospitals. Between 2003 and 2011, the number of physicians and dentists employed by hospitals grew by 55 percent.<sup>1</sup>

Such consolidation has a direct impact on beneficiary cost-sharing. Medicare and beneficiaries pay significantly more for the same service provided in an outpatient department versus a free-standing physician office. Using a 15-minute evaluation and management code as an example, a beneficiary would be assessed a copayment of \$14.50 for the service if it were provided in a free-standing physician office versus \$24.68 for the same service if it were provided in an outpatient department.<sup>2</sup> In addition to higher copayments, the payment differentials also impact overall program spending and thus would result in higher beneficiary premiums. Further, the payment differentials create an incentive for more services to be provided in higher cost settings which also impacts both program and beneficiary out-of-pocket costs.

As CMS collects this data, we urge the Agency to conduct specific analysis on the impact of such consolidation on Medicare beneficiary cost-sharing – both in the form of premiums as well as co-payments.

### **E. Medicare Telehealth Services**

CMS proposes to add seven CPT and HCPCS codes to the list of telehealth services:

- CPT codes 90845 (Psychoanalysis); 90846 (family psychotherapy (without the patient present), and 90847 (family psychotherapy (conjoint psychotherapy) with patient present)
- CPT codes 99354 (prolonged service in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour (list separately in addition to code for office or other outpatient evaluation and management service) and 99355 (prolonged service in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minute (list separated in additional to code for prolonged service); and,
- HCPCS codes G0438 (annual wellness visit; include a personalized prevention plan of service (pps), initial visit) and G0439 (annual wellness visit, includes a personal plan of service (pps), subsequent visit).

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<sup>1</sup> Medicare Payment Advisory Commission. Report to Congress: Medicare and the Health Care Delivery System. June 2013 (Chapter 2: Medicare Payment Differences Across Ambulatory Settings).

<sup>2</sup> Id.

ACS CAN supports CMS' proposed expansion of Medicare's coverage of telehealth services. Approximately one-fourth of all Medicare beneficiaries live in isolated or rural areas<sup>3</sup> and many confront formidable barriers to quality cancer care. Individuals with cancer – particularly those in rural or frontier areas – often have challenges accessing specialists or oncology services due to geographic limitations. Telehealth services can help cancer patients overcome geographic limitations to access specialist care and allow patients the opportunity to receive services without having to incur additional travel costs. Some providers and health care systems are testing models specifically targeted to cancer patients<sup>4,5</sup> especially for delivering palliative care, pain management and patient navigation services.<sup>6,7,8,9</sup>

As health information technology advances, more health care services may be ripe for inclusion within the Medicare telehealth program. We urge CMS to continue to explore additional services that may be appropriate for inclusion in the Medicare telehealth program. Specifically ACS CAN urges CMS to explore the feasibility of adding palliative care services to the telehealth program. The goal of palliative care is to improve the quality of life for the patient (as well as his/her family and/or caregivers) by supporting complex medical decision making, assisting with care planning, and providing psychological and other support. Palliative care provides patients proper management of pain, nausea, fatigue, and other symptoms of their disease or condition. Research has demonstrated that beneficiaries whose care is managed by palliative care professionals have reduced hospitalizations or re-hospitalizations.<sup>10</sup> Expanding the telehealth program to include palliative care services will improve beneficiary access to these vital services.

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<sup>3</sup> Medicare Payment Advisory Commission, A Data Book: Health care spending and the Medicare program. June 2013.

<sup>4</sup> Doolittle GC, Spaulding AO. Providing Access to Oncology Care for Rural Patients via Telemedicine. *J Oncol Pract.* Sep 2006; 2(5): 228-230.

<sup>5</sup> Doorenbos, A.Z., Demiris, G., Towle, C. et al. Developing the Native People for Cancer Control Telehealth Network. *Telemed J E Health.* 2011; 17: 30–34.

<sup>6</sup> Alaska Native Tribal Health Consortium. AFHCAN telehealth solutions. <http://www.afhcan.org/>. Accessed June 21, 2012.

<sup>7</sup> Hennemann-Krause L1, Lopes AJ1, Araújo JA2, Petersen EM2, Nunes RA1. The assessment of telemedicine to support outpatient palliative care in advanced cancer. *Palliat Support Care.* 2014 Aug 27:1-6.

<sup>8</sup> Pruthi S., Stange K.J., Malagrino Jr. G.D., Chawla K.S., LaRusso N.F., Kaur J.S. Successful implementation of a telemedicine-based counseling program for high-risk patients with breast cancer *Mayo Clinic Proceedings*, 88 (1) , pp. 68-73.

<sup>9</sup> Holland DE1, Vanderboom CE, Ingram CJ, Dose AM, Borkenhagen LS, Skadah P, Pacyna JE, Austin CM, Bowles KH. The feasibility of using technology to enhance the transition of palliative care for rural patients. *Comput Inform Nurs.* 2014 Jun;32(6):257-66.

<sup>10</sup> For example, a 2008 study of eight diverse hospitals showed that palliative care consultations resulted in adjusted net savings of \$1,696 in direct costs per admission and \$279 in direct costs per day, including significant reductions in laboratory and ICU costs. Morrison RS, Penrod JD, Cassel JB, Caust-Ellenborg M, Litke A, Spragens L, Meier DE. Cost savings associated with hospital palliative care consultation programs. *Arch Intern Med* 168(16)1783-1790 (2008). Similarly, a 2011 study found that Medicaid patients at four New York hospitals who received integrated palliative care consultations incurred \$6,990 less in hospital costs during a given admission, spent less time in intensive care, and were less likely to die in the ICU. Morrison RS, Dietrich J, Ladwig S, Quill T, Sacco J, Tangeman T, Meier DE. Palliative care consultation teams cut hospital costs for Medicaid beneficiaries. *Health Affairs* 30(3)454-463 (2011).

Finally, in future years as CMS redesigns the telehealth program, we urge the Agency to examine the feasibility of incorporating patient navigation services into the telehealth program. Patient navigation is individualized assistance offered to patients, their families and caregivers that help them overcome barriers and facilitate timely access to medical care. Research has demonstrated that patients who utilize patient navigation services experience better health outcomes and lower health care costs.<sup>11</sup>

### **G. Chronic Care Management**

In its CY2014 rule, CMS announced a policy to pay for chronic care management services furnished to Medicare beneficiaries who have two or more chronic conditions. Specifically, CMS designed the new code to pay separately for non-face-to-face care coordination services and adopted the following code for reporting these services:

*GXXX1* Chronic care management services furnished to patients 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, acute exacerbation/decompensation, or functional decline; 20 minutes or more; per 30 days.

ACS CAN applauds CMS for recognizing that care coordination is critical to ensuring that patients with multiple chronic conditions (like cancer) receive high quality health care. Care coordination is particularly important for cancer patients as they frequently have to navigate between multiple providers and different care settings during the course of their treatment. Research has shown that care coordination at each phase along the continuum of cancer care is vitally important for patients.<sup>12</sup> Conversely, a lack of care coordination for cancer patients has been shown to result in lower quality of care for cancer patients.<sup>13</sup>

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<sup>11</sup> Freund KM1, Battaglia TA1, Calhoun E1, Darnell JS1, Dudley DJ1, Fiscella K1, Hare ML1, LaVerda N1, Lee JH1, Levine P1, Murray DM1, Patierno SR1, Raich PC1, Roetzheim RG1, Simon M1, Snyder FR1, Warren-Mears V1, Whitley EM1, Winters P1, Young GS1, Paskett ED1; Writing Group of the Patient Navigation Research Program. Impact of patient navigation on timely cancer care: the Patient Navigation Research Program. *J Natl Cancer Inst.* 2014 Jun 17;106(6):dju115.

<sup>12</sup> Hewitt M, Greenfield S, Stovall, eds. Committee on Cancer Survivorship: Improving Care and Quality of Life, Institute of Medicine, National Research Council. *From Cancer Patient to Cancer Survivor: Lost in Translation.* Washington, DC: National Academies Press; 2006.

<sup>13</sup> Bowles EJA, Tuzzio L, Wiese CJ, et al. Understanding High-Quality Cancer Care: A Summary of Expert Perspectives. *Cancer*, 2008; 112(4): 934-942.

1. *Valuation of CCM Services – GXXX1*

In order to achieve proper chronic care management, providers must be committed to making a real effort to ensure that chronic care management is an integral part of their practice. Such efforts can take time and a commitment of investment.<sup>14</sup> However, research has demonstrated that when such investments and commitments have been made, there is the potential for health care savings.<sup>15</sup> Some have suggested that CMS' current valuation of CCM services may be inadequate to encourage providers to engage in much-needed chronic care management services. We urge CMS to ensure its valuation of the CCM services provide a reimbursement that accurately reflects the services being provided to beneficiaries, particularly in light of the requirements CMS is imposing on providers to be able to obtain reimbursement for this code. As CMS implements this new code in CY 2015 and beyond we urge the Agency to continue to monitor the valuation of the code to ensure Medicare beneficiaries are being offered comprehensive care coordination services.

2. *Chronic Care Management and Transitional Care Management Services Furnished Incident to a Physician's Service Under General Physician Supervision.*

ACS CAN supports the proposal to remove the requirement that, in order to count the time spent by clinical staff providing aspects of CCM services toward the CCM requirements, the clinical staff person must be a direct employee of the practitioner or the practitioner's practice. Care management teams often include social workers and others who are not employed by the practice. These individuals are integral players in care management and ASC CAN strongly encourages their use.

3. *Scope of Services and Standards for Chronic Care Management Services*

ACS CAN also supports the proposed scope of service requirement that CCM services must be furnished with the use of an electronic health record (EHR) 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 those furnishing care outside of normal business hours, and that is available to be shared electronically with care team members outside of the practice.

As CMS implements this code, we encourage the Agency to examine the feasibility of requiring providers to include additional patient navigation services and palliative care services.

*Patient Navigation Services:* Patient navigation is individualized assistance provided to patients, families, and caregivers to help them overcome barriers and facilitate timely access to quality medical and psychosocial care.<sup>16</sup> Patient navigation services can be performed by a variety of health care professionals who assist the patient with a variety of services from managing appointment, translating information, and completing medical forms to making arrangements for transportation to appointments and securing lodging services during times of treatment. Health systems across the nation prove that

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<sup>14</sup> Bodenheimer T, Berry-Millett R. Care Management of Patients with Complex Health Care Needs. Robert Wood Johnson Foundation. *The Synthesis Project* Dec. 2009, available at [http://www.rwjf.org/content/dam/farm/reports/issue\\_briefs/2009/rwjf49853/subassets/rwjf49853\\_1](http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2009/rwjf49853/subassets/rwjf49853_1).

<sup>15</sup> Holahan J, Schoen C, McMorrow S. The Potential Savings from Enhanced Chronic Care Management Policies. Urban Instit. Nov. 2011, available at <http://www.urban.org/uploadedpdf/412453-The-Potential-Savings-from-Enhanced-Chronic-Care-Management-Policies-Brief.pdf>.

<sup>16</sup> Calhoun E, Esparaza A, Freeman H, Rodriguez R, eds. National Patient Navigation Leadership Summit (NPNSL): Measuring the Impact and Potential of Patient Navigation, Supplement to *Cancer*, 117(15):3605.

patients who used patient navigators had better health outcomes and reduced health care expenditures through lower hospital readmissions or admissions, improved timely diagnostic resolution and prescription drug adherence.<sup>17</sup>

Currently, the CCM services include requirements such as 24/7 access to care management services and enhanced opportunities for a beneficiary (and her caregiver) to communicate with the practitioner. Additional patient navigation services will not only improve the quality of care for patients, but also have the potential to reduce health care costs. As this new code is fully implemented, CMS should evaluate the extent to which providers who utilize the code already are providing additional patient navigation services as part of their practice. This information can help inform CMS of additional patient navigation services that could be added to the requirements without overly burdening providers to the point where they may reconsider utilizing the CCM code.

*Palliative Care Services:* Palliative care is provided by a team of health care professionals that provide patients with relief from the symptoms, pain, and stress of serious illness. Research has demonstrated the use of palliative care services can not only improve the quality of care for a patient, but can result in reduced health care expenditures by reducing hospitalizations or re-hospitalizations. The use of palliative care services has increased in recent years.

As CMS conducts evaluation of the chronic care management code, we encourage the Agency specifically to evaluate the extent to which providers utilize palliative care services as part of their chronic care management services. This information will be helpful to CMS to determine whether in future years the chronic care management code should be revised to specifically encourage providers to more fully utilize palliative care services as part of their practice.

#### *4. Payment of Chronic Care Management Services in CMS Models and Demonstrations*

CMS proposes that practitioners participating in the Multi-Payer Advanced Primary Care Practice Demonstration or the Comprehensive Primary care Initiative may not bill Medicare for CCM services furnished to any beneficiary attributed to either of these initiatives. Providers would be permitted to bill for CCM services provided to beneficiaries who are not attributed to either of these initiatives.

ASC CAN supports CMS' proposal and agree with CMS that the payment for CCM services would essentially constitute a duplicative payment for the same service. Such duplicative payments are harmful to the overall solvency of the Medicare program and unnecessarily increase beneficiary cost-sharing. In addition, duplicative payments undermine the ability to properly evaluate success of the two initiatives.

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<sup>17</sup> Jandorf L, Stossel LM, Cooperman JL, GraffZivin J, Ladabaum U, Hall D, Thélémaque LD, Redd W, Izkowitz SH. Cost analysis of a patient navigation system to increase screening colonoscopy adherence among urban minorities. *Cancer* 2013 Feb 1; 119(3):612-20; Donaldson EA, Holtgrave DR, Duffin RA, Feltner F, Funderburk W, Freeman HP. Patient navigation for breast and colorectal cancer in 3 community hospital settings: an economic evaluation. *Cancer* 2012 Oct 1;118(19):4851-9.

## **H. Definition of Colorectal Cancer Screening Tests**

Citing a recent Journal of the American Medical Association study finding that more than 52 percent of colonoscopies are conducted using anesthesia,<sup>18</sup> CMS proposes to amend the definition of colorectal cancer screening tests to include anesthesia separately furnished in conjunction with screening colonoscopies.

Colorectal cancer is the third most common cancer and cause of death from cancer in both men and women. In 2014, an estimated 137,000 people will be diagnosed with colorectal cancer and over 50,000 will die from the disease.<sup>19</sup> In the Medicare population, colorectal cancer is the second leading cause of cancer related deaths.<sup>20</sup> Colorectal cancer accounted for nearly 11 percent of Medicare fee-for-service cancer payments in 2011.<sup>21</sup>

Treatment costs for colorectal cancer can be very high, particularly for advanced forms of the disease. Estimates suggest that about \$12.2 billion is spent on treatment for colorectal cancer each year in the United States, and annual treatment costs for an advanced case may exceed \$300,000 for a year.<sup>22</sup> However the costs associated with advanced treatment and premature deaths due to colorectal cancer are largely avoidable. Most colorectal cancers result from abnormal growths (“adenomatous polyps”) in the lining of the colon that becomes cancerous over time.<sup>23</sup> Most of these polyps can be identified and removed during a colonoscopy; thus, in many cases, colorectal cancer is preventable through timely screening.<sup>24</sup>

Due to the importance of this public health issue, over 100 health-related organizations have committed to increase the nation’s colorectal cancer screening rate to 80 percent by the year 2018. To achieve this goal, we must remove the obstacles that prevent Americans from getting tested. Despite Medicare’s coverage of screening colonoscopy, the number of beneficiaries who are up to date on recommended colorectal cancer screening is below our goal of 80 percent screened. In 2010, one in three people over age 65 were not up to date with their recommended colorectal cancer screenings.<sup>25</sup> One of the barriers to beneficiaries receiving important preventive screenings and services is cost. To increase adherence to preventive services, the Affordable Care Act (ACA) eliminates Medicare Part B cost-sharing requirements (coinsurance and deductible) for screening tests that have an “A” or “B” rating from the U.S. Preventive Services Task Force (USPSTF). For adults age 50 to 75, colonoscopy has an “A” rating. In spite of changes made by the ACA, Medicare continues to require beneficiaries to pay coinsurance when the

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<sup>18</sup> Liu H, Waxman DA, Main R, Mattke S. Utilization of Anesthesia Services During Outpatient Endoscopies and Colonoscopies and Associated Spending in 2003-2009. *JAMA*. 2012;307(11):1178-1184.

<sup>19</sup> American Cancer Society, *Cancer Facts and Figures 2014*, available at <http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2014/>.

<sup>20</sup> National cancer for Health Statistics, Prepared by the Surveillance and Health Services Research Program of the American Cancer Society, 2012.

<sup>21</sup> Medicare five percent sample LDS SAF files, 2011. Analysis by Direct Research, LLC.

<sup>22</sup> A Snapshot of Colorectal Cancer. American Cancer Society, 2012, available at <http://www.cancer.org/aboutnci/servingpeople/snapshots/colorectal.pdf>.

<sup>23</sup> Winawer SJ. Natural history of colorectal cancer. *Am J Med* 1999;106:3S-6S; discussion 50S-1S.

<sup>24</sup> Zauber AG, Winawer SJ, O’Brien MJ, et al. Colonoscopic polypectomy and long-term prevention of colorectal-cancer deaths. *N Eng J Med* 2012;366:687-96.

<sup>25</sup> American Cancer Society, *Cancer Prevention and Early Detection Facts and Figures*, 2013.

preventive action of removing a polyp, abnormal growth, or suspicious-looking tissue occurs during a screening colonoscopy.

We appreciate and support that CMS has proposed to remove coinsurance for separately billable anesthesia services provided in conjunction with a screening colonoscopy with aim of removing financial barriers to screening. However, we don't believe this is adequate. Under current Medicare policy, beneficiaries are still required to pay co-insurance for screening colonoscopies that include polyp removal or biopsy.

Medicare's current cost-sharing policy is confusing to beneficiaries, and the threat of out-of-pocket costs can serve as a deterrent to screening. In fact, in the current proposed rule, CMS acknowledges that costs associated with colorectal cancer screening present a "significant barrier" to this "essential" preventive service. CMS further notes in the proposed rule that the goal of waiving the Part B deductible and coinsurance was to "eliminate financial barriers so that beneficiaries would not be deterred from receiving them." Given CMS' statements and the intent of the ACA, ACS CAN urges CMS to identify a way under its existing authority to redefine colorectal cancer screening to include screening colonoscopy with removal of polyp, abnormal growth or tissue during the screening encounter.

Many beneficiaries are already surprised to learn they owe coinsurance for a screening colonoscopy with polyp removal. Based on our understanding of the proposal, beneficiaries who choose separately billable anesthesia for their screening colonoscopy under the assumption that it will be covered without cost sharing will be surprised to learn that they are liable for coinsurance for both the colonoscopy and anesthesia when a polyp is removed. The proposed rule as written is not clear in this regard, nor is it clear how the deductible will be treated for the anesthesia services when a polyp or other tissue is removed during a screening colonoscopy.

While the Administration purports colorectal cancer screening to be a "free" preventive service, for nearly half of beneficiaries who choose colonoscopy as their method of colorectal cancer screening, coinsurance will apply. Recent analysis has indicated that nearly half of all patients who undergo screening colonoscopy have a polyp or other tissue removed.<sup>26,27</sup> CMS' current policy is not only unfair, but disproportionately affects lower income beneficiaries because they are most likely to lack supplemental insurance coverage to defray the expense of these unexpected out-of-pocket costs. This is also the population which has the lowest current participation in colon screening services. Therefore, we strongly urge CMS to correct this major barrier for accessing colorectal cancer screening in the CY 2015 Medicare PFS final rule.

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<sup>26</sup> Wolf HJ, Masias A. Cumulative Evaluation Report for the Colorado Colorectal Screening Program, June 1, 2006 – June 14, 2010. Project Deliverable for the Colorado Colorectal Screening Program Funded by the Cancer, Cardiovascular and Pulmonary Disease Grant program. Denver: Colorado Department of Public Health and Environment. 2010.

<sup>27</sup> GI Quality Improvement Consortium Ltd. GIQuIC data registry: A joint initiative of the American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE) In; 2012.

### **I. Payment for Secondary Interpretation of Images**

The proposed rule seeks comment on whether and under what circumstances CMS should permit payment under the fee schedule in instances where physicians furnish subsequent interpretations of existing images. CMS also seeks input on whether such a policy would likely reduce the need for a duplicative imaging study.

ACS CAN appreciates the opportunity to comment on this proposed policy. We believe that allowing a payment for a second interpretation of imaging services could decrease the necessity for a second imaging procedure, which would not only spare beneficiaries – particularly cancer patients – from having to undergo a duplicate test, but also could result in decreased health care costs. For example, second reading of screening mammograms has shown to be effective in detecting additional cancer cases.<sup>28</sup> In addition, secondary interpretations can also increase care coordination between providers and thus should be encouraged.

We urge that CMS clarify that second reading of preventive services (mammograms, low-dose computed tomography) would include a waiver of cost sharing for beneficiaries. It is critical that financial barriers are eliminated for beneficiaries to ensure appropriate utilization of evidence-based preventive services.

However, we note concern that expanding payment for secondary interpretations of images has the potential to be misused and could unnecessarily increase costs for the program and beneficiaries in the form of cost-sharing and premiums. Therefore, we urge CMS as it finalizes this policy to maintain vigilant monitoring of this expanded service to determine appropriate utilization of imaging services.

### **III. Other Provisions of the Proposed Regulations**

#### **D. Removal of Employment Requirements for Services Furnished “Incident to” Rural Health Clinics (RHC) and Federally Qualified Health Center (FQHC) Visits**

CMS proposes to remove the existing requirement that services furnished incident to a rural health clinic (RHC) or a federally qualified health center (FQHC) must be furnished by an employee of the RHC or FQHC. CMS proposes to expand the “incident to” requirement to appropriate health care professionals (e.g., nurse practitioner, physician assistant, certified nurse-midwife, clinical psychologist, and clinical social worker) who contract with the RHC or FQHC.

ACS CAN supports the proposed policy. Community health centers – including FQHCs and RHCs – provide essential community-oriented primary care in areas that are underserved or lack other health care services. Unfortunately many community health centers are unable to fully employ a multi-disciplinary staff and therefore often contract with individual professionals in order to be able to offer necessary services to its patients. Absent the proposed policy, Medicare beneficiaries may not be able to receive necessary services from these health care professionals simply because the professionals are contract employees rather than fully employed individuals.

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<sup>28</sup> Duijm LE1, Groenewoud JH, Fracheboud J, de Koning HJ. Additional double reading of screening mammograms by radiologic technologists: impact on screening performance parameters. *Natl Cancer Inst.* 2007 Aug 1;99(15):1162-70. Epub 2007 Jul 24.

**E. Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models**

CMS proposes to establish requirements that states and other entities participating in Center for Medicare and Medicaid Innovation (CMMI) grants and demonstration projects collect and report information that CMS has determined is necessary to monitor and evaluate such models. The preamble notes that some of the information provided will be individually identifiable health information.

ACS CAN supports the proposed policy which we believe will help CMMI better evaluate its grants and demonstrations. While CMMI would be receiving patient identifiable health information, we urge CMMI to ensure that this information remains subject to the same privacy protections. For example, CMMI should request and use only the information necessary for evaluation and any information must be protected.

**I. Reports of Payments or Other Transfers of Value to Covered Recipients**

CMS proposes to amend the Physician Payment Sunshine Act regulations to eliminate the current exclusion for certain continuing education events on the grounds that the current policy may give the unintended appearance of CMS endorsing or supporting the continuing education events of some accrediting organizations over others. CMS also points out that the exclusion is redundant, as excluded continuing education events would also qualify more generally as excluded indirect payments or transfers of value. In addition, CMS also proposes some minor changes for device manufacturer reporting.

ACS CAN appreciates CMS' willingness to modify the Physician Payment Sunshine Act reporting requirements and CMS' recognition that a manufacturer's conveyance of "full discretion" to a third party is a critical element in the determination of whether a payment is within the scope of the rule. As this new reporting program is implemented, we urge CMS to provide additional guidance to covered entities to clarify reporting requirements related to indirect payments or transfers of value. As a practical matter, there appears to be wide variation among covered entities with respect to implementation of these new policies. Absent detailed and specific guidance from CMS, some covered entities have erred on the side of being overly restrictive with respect to their dealings with physicians. While we recognize that CMS may be somewhat hampered by the statute, additional specific guidance to covered entities will be helpful to ensure more reasonable compliance with the spirit and letter of the regulations.<sup>29</sup>

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<sup>29</sup> One notable blog post describing some of the practical implications of such sunshine law discussed the lengths vendors at a widely attended event would go through to prevent some physicians from receiving a free cup of coffee so as to avoid sunshine act reporting requirements. Lichtenfeld L, Ban The (Free) Coffee! (June 5, 2010), available at <http://www.cancer.org/aboutus/drlensblog/post/2010/06/05/ban-the-free-coffee!.aspx>.

**N. Value-Based Payment Modifier and Physician Feedback Program**

Beginning January 1, 2015, CMS is required to apply a value-based payment modifier (VM) to specific physicians and groups of physicians (physician practices of 100 or more eligible professionals). Beginning January 1, 2017, the VM will be extended to all physicians (and other eligible professionals if determined by Secretary). The VM is meant to provide a differential payment based on the quality and cost of care physicians provide to Medicare beneficiaries.

ACS CAN supports efforts that reward the value rather than the volume of services provided. We are concerned that the VM has the potential to negatively impact physicians (and eligible professionals) that treat high-cost patients (such as cancer patients). We urge CMS to ensure that the VM does not inadvertently create a disincentive for physicians (and eligible professionals) to provide high-quality care to beneficiaries who may require high-cost services.

**Conclusion**

On behalf of the American Cancer Society Cancer Action Network we thank you for the opportunity to comment on the proposed rule. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at [Anna.Howard@cancer.org](mailto:Anna.Howard@cancer.org) or 202-585-3261.

Sincerely,

A handwritten signature in blue ink, appearing to read "Kirsten Sloan", is placed over a light yellow rectangular background.

Kirsten Sloan  
Senior Policy Director  
American Cancer Society Cancer Action Network