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The American College of Gastroenterology (ACG) appreciates the opportunity to provide comments in response to the Senate Finance and House of Representatives Ways & Means Committees' (Committees) discussion draft on Medicare reimbursement reform released on October 30, 2013. ACG applauds the Committees and Congress for undertaking this important and necessary initiative.

ACG is an organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, our organization currently numbers over 12,000 members. The primary activities of ACG have been, and continue to be, promoting evidence-based medicine and optimizing quality of patient care.

Quality Improvement Registries: Linking Measure-Development and Measure-Adherence

In an effort to work with our members to provide the highest quality of care to patients in gastroenterology, ACG and the American Society for Gastrointestinal Endoscopy (ASGE) created the "GI Quality Improvement Consortium" (GIQuIC), a specialty-specific clinical registry. This collaborative effort allows gastrointestinal (GI) specialists to submit data that is relevant to their specialty and receive feedback data that compares their performance with that of their peers. In July 2010, GIQuIC began collecting quality indicators for colonoscopy, as colonoscopy is by far the most common procedure in gastroenterology, especially within the Medicare program. Our organizations are very encouraged by the registry's success to date. As of October 2013, GIQuIC has more than 1,500 physicians from more than 175 practice settings participating in the registry and more than 390,000 cases are in the database. All data in GIQuIC is encrypted and stripped of personally-identifiable patient information.

Participants upload de-identified patient data to the registry, and, in return, receive access to reports on their own performance. They also have the ability to compare their quality performance to regional standards, national standards, and the entire database all on a real-time basis. The registry recently added quality metrics on esophagogastroduodenoscopy (EGD), perhaps the second most common procedure performed by our members, increasing the number of quality metrics reportable through GIQuIC to twenty-three. In the near future, GIQuIC will also be collecting metrics data on endoscopic retrograde cholangiopancreatography (ERCP), patient satisfaction as well as facility-unit related measures.

How can registries further the Committees' objectives for each component of this proposed value-based purchasing (VBP) program?

ACG commends Congress for passing the American Taxpayer Relief Act of 2012, which includes language requiring the Centers for Medicare and Medicaid Services (CMS) to develop a plan to align Medicare

quality reporting using clinical registries. ACG believes that we are only beginning to see the utility and power of patient registries in quality improvement as well as reimbursement reform. The registry is the one common denominator in various proposals to improve quality, improve patient outcomes, reform Medicare reimbursement, reduce overutilization, and reduce administrative burdens associated with various Medicare quality reporting programs.

Many specialty societies want to help Congress and encourage linking reimbursement to quality reporting—as long as there is an opportunity for stakeholders to define "quality" in our respective areas of medicine. Stakeholder collaboration is crucial in any effort to reform Medicare and achieve structural and behavioral change, including the adoption of alternative payment models (APMs) as quality reporting will also be the central component of any forthcoming Medicare reimbursement model.

Quality measures: ACG views the registry as the bridge between measure-development and measure-adherence. Every day an estimated 10 percent of all the clinical gastroenterologists in the country are using the GIQuIC registry to improve quality of care based upon metrics rooted in medical science and accepted principles within our field of medicine. Registries collect the data and report quality information to third parties such as Medicare and commercial insurers. Registries are also used in medical schools and teaching hospitals to educate future physicians. Despite the success registries have achieved in improving quality and efficiency in health care, current Medicare quality reporting programs such as PQRS continue to have low adoption rates even as Medicare reimbursement cuts loom for those not successfully participating.

Participating in clinical quality improvement registries should satisfy the "quality" component of the newly constructed VBP program as proposed by the Committees. Congress can ensure this by expanding the language in the American Taxpayer Relief Act of 2012.

Suggested revisions to the American Taxpayer Relief Act of 2012

In order to assist the Committees in allowing registries to be used to improve the quality of care provided to Medicare beneficiaries, ACG suggests the following revisions to the American Taxpayer Relief Act of 2012: **(suggested changes are underlined and in bold font)**

(b) Advancement of Clinical Data Registries To Improve the Quality of Health Care-

(1) IN GENERAL- Section 1848(m)(3) of the Social Security Act (42 U.S.C. 1395w-4(m)(3)) is amended--

(D) SATISFACTORY REPORTING MEASURES THROUGH PARTICIPATION IN A QUALIFIED CLINICAL DATA REGISTRY- For 2014 and subsequent years, the Secretary shall treat an eligible professional as satisfactorily submitting data on quality measures under subparagraph (A) if, in lieu of **participating in and** reporting measures under subsection (k)(2)(C), the eligible professional is satisfactorily participating in **[the new VBP program],** as determined by the Secretary, in a qualified clinical data registry (as described in subparagraph (E)) for the year.

(E) QUALIFIED CLINICAL DATA REGISTRY-

(i) IN GENERAL- The Secretary shall establish requirements for an entity to be considered a qualified clinical data registry. Such requirements shall include a requirement that the entity provide the Secretary with such information, at such times, and in such manner, as the Secretary determines necessary to carry out this subsection.

(ii) CONSIDERATIONS- In establishing the requirements under clause (i), the Secretary shall consider whether an entity--

(I) has in place mechanisms for the transparency of data elements and specifications, risk models, and measures;

(II) requires the submission of data from participants with respect to multiple payers;

(III) provides timely performance reports to participants at the individual participant level; and

(IV) supports quality improvement initiatives for participants.

(iii) MEASURES- With respect to measures used by a qualified clinical data registry--

(I) sections 1890(b)(7) and 1890A(a) shall not apply; and

(II) measures endorsed by the entity with a contract with the Secretary under section 1890(a) may be used.

(III) measures or metrics developed or endorsed by professional organizations and used in nationally recognized specialty-specific clinical data registries.

(iv) CONSULTATION- In carrying out this subparagraph, the Secretary shall consult with interested parties.

(v) DETERMINATION- The Secretary shall establish a process to determine whether or not an entity meets the requirements established under clause (i). Such process may involve one or both of the following:

(I) A determination by the Secretary.

(II) A designation by the Secretary of one or more independent organizations to make such determination.

Suggested revisions to 42 U.S.C. 1395w-4(m)(3)

ACG also recommends the following changes to 42 U.S.C. 1395w-4(m)(3): **(suggested changes are underlined and in bold font)**

(3) Satisfactory reporting and successful electronic prescriber described

(A) In general

For purposes of paragraph (1), an eligible professional shall be treated as satisfactorily submitting data on quality measures for covered professional services for a reporting period (or, for purposes of subsection (a)(8), for the quality reporting period for the year) if quality measures have been reported as follows:

(i) Three or fewer quality measures applicable If there are no more than 3 quality measures that are provided under the physician reporting system and that are applicable to such services of such professional furnished during the period, each such quality measure has been reported under such system in at least 80 percent of the cases in which such measure is reportable under the system.

(ii) Four or more quality measures applicable If there are 4 or more quality measures that are provided under the physician reporting system and that are applicable to such services of such professional furnished during the period, at least 3 such quality measures have been reported under such system in at least 80 percent of the cases in which the respective measure is reportable under the system.

For years after 2008, quality measures for purposes of this subparagraph shall not include electronic prescribing quality measures.

(iii) Or as otherwise determined by the Secretary pursuant to paragraph D of this section (42 U.S.C 1395w-4(m)(3)(D))

Resource Use: CMS and Congress will look towards the VBP program to assess both quality and cost of delivering that care. Under the current value-based purchasing modifier program, successful participation in PQRS is the first step in meeting VBP program requirements. This is therefore another integral role that registries can play in furthering the VBP program.

Under the Committees' proposal, Medicare claims data would be available to assist physicians to better assess quality improvement activities. The registry is a logical place to warehouse this information as it already collects the relevant quality data. The registry could be expanded to integrate Medicare claims and cost data with quality data, and thus, more accurately assess value-based care based on "apples to apples" quality data vs. cost data.

The utility of registry data in assessing programmatic costs is well documented. According to CMS statistics, more than 290,000 screening colonoscopies for average-risk Medicare beneficiaries (not at high risk of colorectal cancer) were performed in 2011 and totaled more than $73 million in Medicare reimbursement to providers.[1] However, a study published in May 2011 looked at a sample of 24,000 screening colonoscopies in Medicare from 2001-2003. The authors found that more than 20 percent of this sample had repeat screenings prior to recommended guidelines (10 years for the average-risk patient) with no justifying explanation.[2] While there may be legitimate clinical reasons for these repeat examinations, registries capturing this information can provide Medicare with helpful data to assess the issue. These types of data can be gleaned from outcome-based registries such as GIQuIC.

Clinical practice improvement activities: With the assistance of registries, Congress and CMS have the ability to better align various clinical practice improvement activities among specialty societies, private payers, as well as for board certification, thereby reducing redundancy. The provider community would welcome this assistance in streamlining various initiatives and quality reporting requirements among payers and accreditation boards. ACG believes this would also lend broader support for this proposal in the provider community.

Specialty societies such as ACG have many initiatives designed to improve care in our field of medicine. As part of our mandate as a non-profit professional organization, ACG members volunteer for many initiatives designed to educate their peers and improve quality of care in gastroenterology. ACG also offers many continuing education and clinical review courses to membership. This component of the VBP program provides an ideal opportunity for ACG members to continue these efforts while working towards meeting VBP program requirements. For example, achieving fellowship-status in a society or participating in initiatives such as authoring clinical guidelines for a specific treatment or condition all require a significant amount of time and dedication. These efforts should be specifically cited in any legislative language as counting towards fulfilling this component.

During the discussion with committee staff on Wednesday, November 6, 2013, specialty societies were asked for recommendations to further align quality improvement programs currently underway within the private payer community and elsewhere. Our registry has partnered with private payers to assess quality of care in their respective states. For example, GIQuIC has partnered with Blue Cross Blue Shield of North Carolina to reward providers for participating in the registry as part of its "Provider Recognition Program."

Recently, the American Board of Internal Medicine (ABIM) revised its "maintenance of certification" or MOC requirements for all ABIM-certified physicians. These changes will add a significant amount of time and financial resources in order to successfully participate in "clinical practice improvement activities" outside of Medicare. Our members continue to express concern and fear over these forthcoming changes. Specifically, ABIM will require all certified physicians beginning in 2014 to

[1] CMS Medicare Part B Summary File; 2011 Payment Claims. http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/PartBNationalSummaryDataFile.html

[2] James S. Goodwin, MD; Amanpal Singh, MD, MS; Nischita Reddy, MD; Taylor S. Riall, MD, PhD; Yong-Fang Kuo, PhD Arch Intern Med. Published online May 9, 2011. doi:10.1001/archinternmed.2011.212

"continuously engage in MOC requirements" in order to maintain good standing. Gastroenterology is a sub-specialty of internal medicine, and according to the website, ABIM certification "has meant that internists have demonstrated – to their peers and the public – that they have the clinical judgment, skills, and attitudes essential for the delivery of excellent patient care."[3] However, it costs our members over $2,000 to be ABIM-certified, another $2,000 for a MOC-activities fee, as well as other fees related to the number of sub-specialties and tests in which physicians wish to designate themselves. The new MOC requirement includes successful participation in "practice improvement modules" or PIMs. A registry can serve to help meet these goals and objectives at the same time as meeting other Medicare quality reporting objectives. Thus, to ease administrative and financial burdens among clinicians and streamline private clinical practice improvement activities, Congress should also specifically incorporate "fulfilling ABIM accreditation and MOC activities" into the legislative language as eligible **clinical practice improvement** activities.

House Energy & Commerce Committee Proposal

Suggested language on "clinical practice improvement activities" per the recent House of Energy & Commerce SGR reform proposal: **(suggested changes are underlined and in bold font)**

CLINICAL PRACTICE IMPROVEMENT ACTIVITIES—

The term 'clinical practice improvement activity' means an activity that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines when effectively executed, is likely to result in improved outcomes**, such as voluntary quality improvement initiatives sponsored by the relevant professional organization that are designed to improve patient outcomes, or initiatives required by third party payers and medical accreditation boards, including fulfilling ABIM accreditation and maintenance of certification activities**.

EHR Meaningful Use: Currently, a provider must report clinical quality measures in the Medicare/Medicaid electronic health record incentive program, or "meaningful use" program, in addition to reporting other clinical quality measures under PQRS. Congress now has the ability to further align clinical quality reporting to ease reporting burdens among Medicare providers. In addition to PQRS clinical quality reporting, providers must report an additional six clinical quality measures in Stage 1 of the "meaningful use" program. This requirement expands to nine measures beginning next year as part of Stage 2 "meaningful use." Now that the Committees seek to align PQRS and "meaningful use" into one VBP program, there is also an opportunity to assess whether an additional clinical quality component is duplicative and unnecessary in "meaningful use," given the discussion draft weights the **quality measures** and **resource use** components higher than any other performance category in this newly designed VPB program. If the Committees and CMS believe the "meaningful use" program should

[3] http://www.abim.org/about/default.aspx

not be altered in this fashion, then ACG urges better program alignment via a registry. There is precedent to do this as well: as part of Stage 2, one "menu option" is for the provider to demonstrate that the EHR can submit data to a clinical quality improvement registry. This should be a "core" measure to ensure EHRs have the technological function of sending quality data to a registry. ACG believes that this technological functionality should be the focus of "meaningful use" – not the quality measure itself as this would be the function of the **quality measures** component (right now, PQRS).

The GIQuIC registry was also developed to be easily incorporated into the electronic health records commonly used by gastroenterologists called endoscopy report writers, or "endowriters," as well as other electronic health records. This ability to electronically transmit all patient records for key physician/patient interactions has been a critical element to easing integration of registry participation into clinical practices. It also helps ensure all cases are uploaded, as to avoid a "cherry-picking" in case reporting, as well as the other data reliability problems that are associated with claims-based data collections. To further ensure accuracy and validity, GIQuIC participants agree to regular audits and reviews to confirm that all relevant data in the patient records are consistent with the data uploaded to the registry.

Suggested revisions to the American Recovery and Reinvestment Act of 2012 (Title IV, section 4104) (HITECH Act) (42 U.S.C 1395w-4(O)(2))

ACG recommends the following changes to the "meaningful use" program **(suggested changes are underlined and in bold font):**

(2) Meaningful EHR user

(A) In general

For purposes of paragraph (1), an eligible professional shall be treated as a meaningful EHR user for an EHR reporting period for a payment year (or, for purposes of subsection (a)(7), for an EHR reporting period under such subsection for a year) if each of the following requirements is met:

(i) Meaningful use of certified EHR technology. The eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period the professional is using certified EHR technology in a meaningful manner, which shall include the use of electronic prescribing as determined to be appropriate by the Secretary.

(ii) Information exchange. The eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.

(iii) Reporting on measures using EHR Subject to subparagraph (B)(ii) and using such certified EHR technology, the eligible professional submits information for such period, in a form and manner

specified by the Secretary, on such clinical quality measures and such other measures as selected by the Secretary under subparagraph (B)(i).

The Secretary may provide for the use of alternative means for meeting the requirements of clauses (i), (ii), and (iii) in the case of an eligible professional furnishing covered professional services in a group practice (as defined by the Secretary). The Secretary shall seek to improve the use of electronic health records and health care quality over time by requiring more stringent measures of meaningful use selected under this paragraph.

(B) Reporting on measures

(i) Selection. The Secretary shall select measures for purposes of subparagraph (A)(iii) but only consistent with the following:

(I) The Secretary shall provide preference to clinical quality measures that have been endorsed by the entity with a contract with the Secretary under section 1395aaa(a) of this title, **as well as section 1395w-4(m)(3)(D) of this title, for the reporting of clinical quality measures**.

(II) Prior to any measure being selected under this subparagraph, the Secretary shall publish in the Federal Register such measure and provide for a period of public comment on such measure.

(ii) Limitation. The Secretary may not require the electronic reporting of information on clinical quality measures under subparagraph (A)(iii) unless the Secretary has the capacity to accept the information electronically, which may be on a pilot basis.

(iii) Coordination of reporting of information. In selecting such measures, and in establishing the form and manner for reporting measures under subparagraph (A)(iii), the Secretary shall seek to avoid redundant or duplicative reporting otherwise required, including reporting under subsection (k)(2)(C) **and subsection (m)(3)(D), when reporting clinical quality measures**.

Is there currently a legislative proposal that provides an example of how registries can reform Medicare reimbursement?

The SCREEN Act: Example of Medicare Reimbursement Reform

ACG recommends that the Committees also look towards current legislative proposals that seek to improve the Medicare reimbursement system. One example is the *Supporting ColoRectal Examination and Education Now" (SCREEN) Act* (HR 1320/S. 608). This legislation, introduced by Senator Ben Cardin and Representative Richard Neal, addresses a number of barriers to colorectal cancer screening utilization by: 1) removing cost-sharing for colorectal cancer screenings that turn into therapeutic procedures (when a polyp is removed); and 2) providing Medicare coverage for beneficiaries to review and discuss the preparation, process, and risks/benefits of the procedure with the physician performing

the colonoscopy.[4] Equally as important, the legislation would increase reimbursement for colorectal cancer screening, contingent upon a provider's participation in a nationally recognized quality improvement registry that measures the physician's performance based on accepted colorectal cancer screening quality metrics. Conversely, Medicare reimbursement is reduced for those providers performing colorectal cancer screening but who are not participating in a quality improvement registry.

The SCREEN Act is an example of moving the Medicare reimbursement system to a more value-based purchasing model. It would not only ensure that providers are demonstrating high quality of care, but also reward Medicare providers for taking the initiative to improve performance.

Conclusion

ACG thanks the Committees and staff for their efforts to reform the Medicare reimbursement model and for seeking our input in this process. ACG is happy to provide physician-experts as needed and welcomes any opportunity to work with you to improve health outcomes and the Medicare system as a whole. Please contact Brad Conway, Vice President, Public Policy, Coverage & Reimbursement, at 301.263.9000 or bconway@gi.org.

[4] In February 2010, the National Institutes of Health (NIH) hosted a "State of the Science" Conference on colorectal cancer screening and cited cost sharing and patient fear as significant barriers to screenings.