



May 17, 2016

Chairman Lamar Alexander
Senate Health, Education, Labor and Pensions Committee
428 Dirksen Senate Office Building
Washington, D.C. 20510

Ranking Member Patty Murray
Senate Health, Education, Labor and Pensions Committee
648 Hart Senate Office Building,
Washington, DC 20510

Re: CMS-5061-P—Medicare Program: Expanding Uses of Medicare Data by Qualified Entities

Dear Chairman Alexander and Ranking Member Murray:

The Physician Clinical Registry Coalition (the Coalition) thanks you for your leadership in making Medicare claims data available to Qualified Clinical Data Registries (QCDRs) for quality improvement purposes under Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The Coalition is a group of more than 20 medical societies and physician-led organizations that have established clinical data registries to collect identifiable patient information for quality improvement and patient safety purposes. These registries help participating providers monitor clinical outcomes among their patients. The Coalition is dedicated to enabling the development of these registries and enhancing their ability to improve quality of care and patient safety outcomes through the analysis and reporting of the data collected. Over half the members of the Coalition have been approved as qualified clinical data registries (QCDRs) and most of the rest are working toward that goal.

The Coalition is writing to express its concern that the Centers for Medicare and Medicaid Services (CMS) did not propose new policies and procedures to implement Section 105(b) of MACRA as part of its *Medicare Program: Expanding Uses of Medicare Data by Qualified Entities*, CMS-5061-P, proposed rule (the Proposed Rule).¹ Under Section 105(b), Congress explicitly directed CMS to provide Medicare claims data to QCDRs for quality improvement and patient safety purposes. CMS instead chose not to adopt policies and procedures to implement this provision, claiming that the process for accessing Medicare claims data outlined on the Research Data Assistance Center (ResDAC) website is already available to QCDRs. In so doing,

¹ Medicare Program: Expanding Uses of Medicare Data by Qualified Entities, 81 Fed. Reg. 5,397 (Feb. 2, 2016), available at <https://www.gpo.gov/fdsys/pkg/FR-2016-02-02/pdf/2016-01790.pdf>.

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CMS ignored the fact that Congress was aware of the ResDAC process when it passed Section 105(b) of MACRA and/or would not have adopted this provision if it thought that CMS was already providing QCDRs with sufficient access to Medicare data through ResDAC or otherwise. For the reasons stated in the Coalition's attached comments on the Proposed Rule, the ResDAC process, which was established to respond to discrete requests for Medicare data from researchers, does not provide the continuous and comprehensive access to Medicare claims data required by QCDRs (and as contemplated by the plain language of Section 105(b)) for purposes of linking outcomes data to claims data in support of their quality improvement efforts. In addition to our comments on the Proposed Rule, we are enclosing a recent article about this issue.

The Coalition thanks you again for your work in directing CMS to make Medicare claims data available to QCDRs for quality improvement purposes. We ask that you clarify with CMS Congress' intent in issuing Section 105(b) of MACRA and urge CMS to initiate additional notice and comment rulemaking to establish a process for QCDRs to access Medicare Claims data for quality improvement purposes in addition to the procedures available through ResDAC. If you have any questions, please contact Rob Portman at rob.portman@ppsv.com or 202-872-6756.

Respectfully submitted,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION

AMERICAN ACADEMY OF NEUROLOGY

AMERICAN ACADEMY OF OPHTHALMOLOGY

AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION

AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS

AMERICAN COLLEGE OF EMERGENCY PHYSICIANS

AMERICAN COLLEGE OF RHEUMATOLOGY

AMERICAN COLLEGE OF SURGEONS

AMERICAN GASTROENTEROLOGICAL ASSOCIATION

AMERICAN JOINT REPLACEMENT REGISTRY

ANESTHESIA QUALITY INSTITUTE/AMERICAN SOCIETY OF ANESTHESIOLOGISTS

AMERICAN SOCIETY OF CLINICAL ONCOLOGY

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AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY

AMERICAN SOCIETY OF PLASTIC SURGEONS

AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

AMERICAN UROLOGICAL ASSOCIATION

GIQUIC/ AMERICAN COLLEGE OF GASTROENTEROLOGY

NORTH AMERICAN SPINE SOCIETY

SOCIETY OF INTERVENTIONAL RADIOLOGY

SOCIETY OF NEUROINTERVENTIONAL SURGERY

SOCIETY FOR VASCULAR SURGERY

THE SOCIETY OF THORACIC SURGEONS

Enclosures

ATTACHMENTS

- Attachment 1 Letter from the Physician Clinical Registry Coalition to Andy Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services regarding [CMS-5061-P] – Medicare Program: Expanding Uses of Medicare Data by Qualified Entities (March 29, 2016)
- Attachment 2 Jacqueline Fellows, Clinical Registry Groups Push for Greater Access to Medicare Claims Data, HEALTH LEADERS MEDIA (April 21, 2016).

Attachment 1



March 29, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-FC, P.O. Box 8013
Baltimore, MD 21244-8013.

Re: [CMS-5061-P] – Medicare Program: Expanding Uses of Medicare Data by Qualified Entities

Dear Mr. Slavitt:

The Physician Clinical Registry Coalition (the Coalition) welcomes the opportunity to comment on the Medicare Program: Expanding Uses of Medicare Data by Qualified Entities Proposed Rule (Proposed Rule). The Coalition is a group of more than 20 medical societies and other physician-led organizations that sponsor clinical data registries that collect identifiable patient information for quality improvement and patient safety purposes to help participating providers monitor clinical outcomes among their patients. We are committed to advocating for policies that enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of these outcomes. Over half the members of the Coalition have been approved as qualified clinical data registries (QCDRs) and most of the others are working toward that goal.

The Coalition commends the Centers for Medicare & Medicaid Services (CMS) for continuing to promote transparency as to Medicare claims data through its development of the Qualified Entity (QE) program and its implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10). The Coalition is disappointed, however, that CMS chose not to develop new policies and procedures to implement Section 105(b) of MACRA. Under Section 105(b), Congress directed CMS to make Medicare claims data available to QCDRs at their request to support their quality improvement and patient safety efforts. However, CMS chose not to issue new regulations addressing Congress' directive as part of the Proposed Rule, stating that QCDRs can already access Medicare claims data through processes outlined on the Research Data Assistance Center (ResDAC) website.

In declining to issue regulations implementing Section 105(b) of MACRA, CMS has ignored the fact that Congress was well aware of the ResDAC processes for accessing data and yet chose to pass Section 105(b) anyway. Congress must have intended for CMS to create processes for accessing Medicare claims data in addition to those that were already available. In fact, Section 105(b) is primarily intended to allow QCDRs access to Medicare claims data for quality

improvement and patient safety purposes, instead of for the discrete research purposes for which the data is already available through the ResDAC processes. The Coalition therefore respectfully requests that CMS issue regulations implementing Section 105(b) of MACRA. We further request that such data sharing policies and procedures include matching of the Medicare claims data to the Social Security Death Masterfile (SSDMF) data before its release to improve the accuracy of QCDR clinical outcomes data.

1. Congress Intended CMS to Issue Regulations Governing the Release of Medicare Claims Data to QCDRs

CMS' decision not to issue regulations implementing Section 105(b) of MACRA is contrary to the plain language of the statute. Section 105(b) explicitly requires that CMS make Medicare claims data available to QCDRs for quality improvement and patient safety purposes. The Coalition advocated for this provision of MACRA so that the clinical outcomes information gathered by QCDRs could be tied to Medicare claims data to better track these outcomes over time. Congress was aware of these benefits when it passed MACRA. It also knew that Medicare claims data was already available to QCDRs for research purposes, yet chose to direct CMS to create an additional avenue for accessing Medicare data for quality improvement purposes. In choosing not to issue regulations implementing this provision, CMS would render Section 105(b) superfluous, an interpretation that is clearly contrary to Congress' intent, the plain meaning of the statute, and longstanding principles of statutory construction.

2. CMS Must Provide QCDRs With Access to Medicare Claims Data for Quality Improvement and Patient Safety Purposes

Congress drafted Section 105(b) specifically to allow QCDRs access to Medicare claims data for quality improvement and patient safety purposes. Section 105(b) is titled "Access to Medicare Claims Data by Qualified Clinical Data Registries to Facilitate Quality Improvement" and the language of the statute explicitly directs CMS to provide Medicare claims data to QCDRs "for purposes of linking such data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses and research *to support quality improvement or patient safety.*" (Emphasis added). In declining to issue regulations implementing this provision, CMS fundamentally misunderstands Congress' intent in passing Section 105(b) of MACRA. According to the preamble to the proposed rule, CMS believes that "[t]he CMS research data disclosure policies already allow qualified clinical data registries to request Medicare data for [Section 105(b)'s] purposes, *as well as other types of research.*" (Emphasis added) However, releasing Medicare claims data for quality improvement and patient safety purposes, as requested by Congress, is distinct from using Medicare claims data for research. Moreover, the distinction drawn by Congress is consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) distinction between research and quality improvement activities with respect to patient identifiable data.

To perform data analysis for quality improvement purposes and patient safety, QCDRs require long-term and continuous access to large Medicare data sets to better track clinical outcomes over time. In drafting Section 105(b) of MACRA, Congress was aware of this need and as such

specifically directed CMS to provide QCDRs with Medicare claims data “for purposes of linking such data with clinical outcomes data.” The ResDAC process that CMS believes addresses this need is cumbersome and provides for the release of data only for discrete research projects. Limiting QCDRs to this process would inhibit their ability to use Medicare claims data to track clinical outcomes over the long-term. Congress instead intended to make Medicare claims data available to QCDRs by virtue of their having met the requirements of the QCDR qualification process. CMS would still need to provide a mechanism for QCDRs to apply to CMS and identify their specific data needs, but this mechanism should be wholly separate from the ResDAC procedures, which are designed to address discrete research projects.

3. SSDMF Data Should be Matched with Medicare Claims Data Before Being Released to QCDRs

In releasing Medicare claims data for QCDRs, CMS should match that data to the state-reported death data in the SSDMF to allow QCDRs to verify the “life status” of patients who otherwise may not be available for follow-up after treatment. The Social Security Administration (SSA) used to have a policy of sharing this data but withdrew it in 2011 for legitimate privacy concerns and as a protection against identity theft. However, the Secretary of Health and Human Services (HHS) also has the authority under 42 U.S.C. § 405(r)(9) to match data held by the SSA to data held by HHS. Matching the SSDMF data to Medicare claims data before releasing it to QCDRs for quality improvement and patient safety purposes would greatly enhance the ability of QCDRs to verify patient death status and track patient outcomes over time.

Conclusion

CMS’ decision not to implement Section 105(b) of MACRA and provide QCDRs with continuous and timely access to Medicare claims data for quality improvement and patient safety purposes is contrary to congressional intent and the plain language of the statute. The ResDAC procedures for accessing Medicare claims data are insufficient to address QCDRs needs. We respectfully request that CMS establish a mechanism for QCDRs to request Medicare claims data for purposes of linking to clinical outcomes data in support of the quality improvement efforts of QCDRs consistent with Section 105(b). We also respectfully request that the Medicare claims data accessed through this process be matched with SSDMF data before it is shared with QCDRs.

Thank you for the opportunity to submit these comments. If you have any questions, please contact Rob Portman at Rob.Portman@ppsv.com or 202.466.6550.

Respectfully submitted,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION
AMERICAN ACADEMY OF NEUROLOGY
AMERICAN ACADEMY OF OPHTHALMOLOGY

Mr. Andrew Slavitt

March 29, 2016

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AMERICAN COLLEGE OF EMERGENCY PHYSICIANS
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AMERICAN SOCIETY OF CLINICAL ONCOLOGY
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SOCIETY OF NEUROINTERNTIONAL SURGERY
SOCIETY FOR VASCULAR SURGERY
THE SOCIETY OF THORACIC SURGEONS

Attachment 2

Clinical Registry Groups Push for Greater Access to Medicare Claims Data

Jacqueline Fellows, April 21, 2016

Medical specialty societies are pushing back on a CMS proposal that they believe will slow down MACRA's goal of improving cost, quality, and outcomes. "To get this [Medicare claims] data and match it to our clinical data is the golden egg," says one physician leader.

While hospital and physician group leaders focused on the broad implications of MACRA (the Medicare Access and CHIP Reauthorization Act of 2015) at a U.S. House committee hearing Tuesday, medical societies are hoping Congress will pay more attention to a tiny section within the proposed rule that they believe could thwart the healthcare industry's ability improve healthcare quality and cost.

The Physician Clinical Registry Coalition (PCRC), a group of more than 20 medical specialty societies and other physician-led organizations, such as the American Academy of Neurology, Society of Thoracic Surgeons and American College of Emergency Physicians, contends that CMS isn't following the spirit of MACRA that grants access to Medicare claims data.

"We think CMS punted in a way that wasn't consistent with congressional intent," says Rob Portman, who coordinates and represents PCRC.

At issue is valuable Medicare claims data, which qualified clinical data registries were given access to in Section 105(b) of MACRA. Claims data is valuable to medical societies, such as the Society of Thoracic Surgeons (STS), because when it is combined with clinical data, physicians can measure patient care, cost, outcomes, and quality over time.



It gets to the heart of providing value-based care, says Jeffrey Jacobs, MD, FACS, FACC, FCCP, chief of cardiac surgery at Johns Hopkins All Children's Heart Hospital and professor of cardiac surgery at Johns Hopkins University. Jacobs chairs STS's workforce on national databases. He says that even though STS maintains the largest heart surgery database in the world, it has limitations.

"STS collects robust clinical data up until the time of hospital discharge and 30 days after the operation, but Medicare data can tell us if someone's still alive five, 10, or 15 years after an operation," Jacobs says. "It can also tell us how many times they were admitted to the hospital, why, how much it cost, and what medications patients received."

In short, Jacobs says, the databases work best together. And, he says the issue isn't just about data.

"If the government wants to find ways to deliver more cost-effective health care, it would seem to be a no-brainer to allow unfettered access to Medicare data by societies," Jacobs says. "This doesn't just apply to heart surgery, it could apply to neurosurgery or psychiatry."

ResDAC vs. Medical Registries

As far as CMS is concerned, it *is* granting access to Medicare claims data. In a [proposed rule](#) released in February, CMS stated that registries, such as the one maintained by STS, could get Medicare claims data through the Research and Data Assistance Center, known as [ResDAC](#).

It's true that ResDAC is a channel for organizations to get the information in question, but Jacobs and others say ResDAC isn't a true alternative to the Medicare claims data spelled out in MACRA.

"It's difficult to access and the data quality is not as good as it could be," says Jacobs.

Former director of CMS's Center for Medicare Management Jeffrey Rich, MD, agrees. Rich, who is past president of STS and currently serves on the board of directors of Virginia Cardiac Surgery Quality Initiatives (VCSQI), says there are several drawbacks to using data from ResDAC.



"It's cumbersome," he says. "You have to apply, qualify, submit your proposal, ask for the data, then pay a fee. And your file upload capabilities are limited to 50 gigabytes; that's not a lot of data."

In response to CMS's interpretation, Portman wrote a [letter on behalf of PCRC](#) pointing out that ResDAC's purpose is for research that uses separate, distinct datasets. MACRA's intent is to link value, cost, quality, and outcomes, which calls for much more dynamic analysis.

"Registries need continuous access to improve the power of their databases," Portman says.

The kind of access that Jacobs and other medical societies want is something that Rich has through VCSQI, a consortium of more than 30 hospitals and cardiac surgery centers in Virginia. The group has worked together since 1996. The 18 VCSQI hospitals share their Medicare claims data with 14 participating cardiac surgical practices.

"Once we get the data back, we do our own aggregation," Rich says. "It's like getting a box of tax receipts at the end of the year to interpret. We hire an IT company, and to do that on annual basis is a quarter of a million dollars. We have a huge infrastructure to do this, but it's really what we need."

By combining Medicare claims data with clinical data, cardiac quality, outcomes, and cost in Virginia have improved. As a result of sharing data, VCSQI developed a standard protocol for reducing post-operative atrial fibrillation. It has also reduced blood transfusions, saving the state at least \$44 million. Now the consortium is working on reducing readmissions, Rich says.

"To get this data and match it to our clinical data is the golden egg," he says. "We've proved there is value in doing it, but nobody can do what we do because of the barriers. That's why we pushed Congress hard for access to the data. It's crucial for value-based purchasing."

[Jacqueline Fellows](#)

Jacqueline Fellows is a contributing writer at HealthLeaders Media.