

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Halt mandatory CMMI models; reaffirm Congress' role in expansion of models

Summary:

The Center for Medicare & Medicaid Innovation (CMMI) is established under Section 1115A of the Social Security Act (SSA). This provision of law does not authorize the Centers for Medicare & Medicaid Services (CMS) to mandate provider participation in CMMI models, such as the Comprehensive Care for Joint Replacement (CJR) model (or the Episode Payment Model (EPM), if it is implemented). Further, under section 1115A, any permanent or mandatory changes to Medicare payment systems must be enacted by Congress after taking into account results of models that have been tested.

The purpose of the CMMI is to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing quality of care, with an emphasis on models that improve coordination, quality, and efficiency of health care furnished to Medicare and Medicaid beneficiaries (§1115A(a)(1) of the SSA). The statute directs the Secretary to select “from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.” (§1115A(b)(1)(A) of the SSA). The law further directs CMS to evaluate each Phase I CMMI model, and only after taking into account this evaluation, if appropriate, the model may continue to be tested in Phase II to expand “the scope and duration”, provided certain requirements are met (§1115A(c) of the SSA), including a requirement for a separate notice and comment rulemaking for any expansion. CMS is required to report periodically to Congress on CMMI models and make proposals for legislative action on models it deems appropriate (§1115A(g) of the SSA).

The language, structure and requirements of section 1115A clearly indicate that Congress did not delegate its lawmaking authority to CMS. Under section 1115A, any permanent or mandatory changes to Medicare payment systems must be enacted by Congress after taking into account results of models that have been tested. Congress is the branch of the Federal government responsible for enacting changes to Medicare payment systems through legislation; CMS is granted limited authority under specific provisions of law to make specific changes to those payment systems or to test new models. There is no language in the statute or any legislative history that supports the interpretation that Congress delegated its authority to make permanent changes to the program to the Secretary through the CMMI. In fact, the limited legislative history on this provision indicates the exact opposite. Notably, nowhere does the law expressly state that CMS can make models mandatory.

Again, mandates on providers of services and suppliers are made through individual legislative enactment; section 1115A does not grant CMS the authority to usurp the role of Congress with

respect to permanent or mandatory changes to the law. Because delegations of lawmaking authority to the agencies may be constitutionally suspect, Congress would have had to include specific statements in the legislation indicating that it both intended to and actually was delegating its lawmaking role to the agency. Any such delegation would have had to include clear standards for the administration of duties to limit the scope of agency discretion as well as procedural safeguards from arbitrariness or abuses. In other words, Congress would have had to specifically permit CMS to require participation of providers of services and suppliers in a model tested by the CMMI in the language of the authorizing statute. CMS may not impute that Congress granted the agency this authority.

This is especially true because Congress precluded administrative or judicial review of a substantial number of matters of CMMI demonstration authority under section 1115A(d)(2) to permit the testing of models. The waivers of administrative or judicial review require that the scope of delegation to the agency be read in the narrowest terms, meaning that the agency may not infer additional grants of authority absent specific language in the statute. Mandating participation of providers of services and/or suppliers contradicts the statutory mandate and raises concerns about impermissible delegation of lawmaking authority to the executive branch.

Related Statute/Regulation:

42 U.S.C. 1315a; Section 1115A of the SSA

Proposed Solution:

Eliminate mandatory CMMI models, such as the CJR model, and make it entirely voluntary. Further, nationwide policy changes to CMMI expansions that would require changes to existing law should receive Congressional approval prior to implementation.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Improvements to CMMI bundling programs:

- Reexamine and recalibrate existing bundling programs
- Implement prospective beneficiary assignment to Medicare ACOs/MSSP
- Increase flexibility in developing preferred provider networks in bundling programs
- Eliminate, or alternatively, streamline/standardize beneficiary notice of hospital participation in bundling programs

Summary:

Reexamine and recalibrate existing bundling programs

Existing Center for Medicare & Medicaid Innovation (CMMI) bundling programs, such as the Comprehensive Care for Joint Replacement (CJR), were rolled out in a manner that is “too much too soon” without the opportunity to evaluate ongoing programs to determine best practices and implement mid-course program adjustments. Even with the recent Proposed Rule from CMS cancelling the Episode Payment Model (EPM) and scaling back mandatory participation in CJR, there is a need to reexamine and recalibrate numerous program requirements to ensure they are operationally feasible and actually improve value-based, coordinated care. Key requirements that should be re-examined and addressed include: providing timely data to providers; length of episodes; stop-loss and stop-gain limits; areas used to establish regional prices; downside risk; target price discount factors; payment flexibility for PAC providers to better achieve efficiencies; appropriate waivers under fraud and abuse laws for gainsharing purposes; gainsharing caps; development of preferred provider networks; and duplicative beneficiary notice requirements.

Implement prospective beneficiary assignment to Medicare Accountable Care Organizations/ Medicare Shared Savings Program (ACOs/MSSP)

For assignment of beneficiaries to an ACO in Track 1 and Track 2 of the MSSP, CMS performs a preliminary prospective assignment that provides ACOs with information about the fee-for-service population that is likely to be assigned to it for the performance year. However, the final list of beneficiaries assigned to the ACO is determined based on a retrospective reconciliation completed after the end of the performance year, which drives the calculations of average per capita expenditures for the performance year. The current retrospective methodology creates significant uncertainty for ACOs, as they are unable to clearly identify the patient population they are responsible for until after the performance year has ended. ACOs are undertaking significant investments to redesign care delivery to better serve patients, and they must have clear information regarding their assigned patient population in order to proactively and effectively serve the patients for whom they are responsible.

Increase flexibility in developing preferred provider networks in bundling programs

In recent years, the value of preferred provider networks has emerged as a critical factor in facilitating care coordination and optimization of care in bundling arrangements/alternative payment models (APMs). Yet, hospital APM participants are required to provide Medicare beneficiaries with a full list of area home health and skilled nursing facilities in the discharge planning process. This is confusing for patients, has little value, and prevents hospitals from highlighting high quality providers that can best coordinate care under an APM arrangement.

Streamline/standardize beneficiary notice of hospital participation in bundling program

Many of our hospital members participate in multiple CMMI bundling programs, such as Bundled Payments for Care Improvement (BPCI) and CJR. Each of these programs has separate and distinct beneficiary notice requirements of the hospitals' participation in the bundling program. The FAH questions the necessity of such notice. We understand the need for beneficiary transparency regarding that hospitals are paid on a bundled basis. However, hospitals have long been paid under the current DRG system – where hospitals are already motivated to contain costs during the hospital stay, and under this system, CMS has not implemented such notice requirements. We believe beneficiary protections afforded by current law are sufficient and that the CJR (and EPM notice requirement, should EPM still be implemented) serve only to burden participating providers and confuse beneficiaries.

Alternatively, if these beneficiary notices are required, they should be streamlined and standardized. Currently, patients may receive notification about hospital participation in BPCI and CJR (and possibly EPM, if it is implemented) and could potentially receive notices from hospital bundling collaborators. Also, BPCI notification is very complicated due to the mix of procedural and medical episodes, and requires a combination of chart review and predictive technology to help identify BPCI patients during their anchor admission. In a scenario where a hospital is in BPCI and CJR (and EPM), it would be very difficult for hospital staff to discern which notice is required for which beneficiary at the appropriate time. Further, the sheer volume of notices is duplicative and may ultimately confuse beneficiaries, particularly those who are later determined by a participant hospital at the time of discharge to be outside of such programs. This complexity, patient confusion, and unnecessary hospital operational burden could be easily resolved through streamlining all CMMI or CMS-led bundled program beneficiary notices into one standardized notice, that could be provided to all Medicare beneficiaries upon admission. The notice also could be incorporated into existing CMS notices, for example, the Important Message notice.

See attached Appendix A for extensive discussion of each of the issues discussed above.

Related Statute/Regulation:

80 Fed. Reg. 73274 (Nov. 24, 2015) (CJR Payment Model)

82 Fed. Reg. 180 (Jan. 3, 2017) (EPM and changes to the CJR)

82 Fed. Reg. 39310 (August 17, 2017) (Cancellation EPM and changes to the CJR)

BPCI, CMS Fact Sheet: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-18.html>

42 U.S.C. 1395jjj (ACOs/MSSP)

81 Fed. Reg. 37950 (Fri, Jun. 10, 2016) (ACOs)

42 U.S.C. 1395x(ee)(2)(H); 42 CFR 482.42(c)(6) – (8) (Patient freedom of choice law)

42 U.S.C. 1395ww(j) (IRF payment system)

42 CFR 412.29 (IRF 60 percent and three-hour rules)

Proposed Solution:

CMS – with robust stakeholder input – should reexamine the CMMI bundling programs, such as the BPCI or CJR, to ensure they are successful in achieving program goals.

Prospectively assign beneficiaries to an ACO in Track 1 and Track 2 of the MSSP.

Waive statutory and regulatory requirements for bundling arrangements/APMs, or adopt a more flexible interpretation of current law, that would permit hospitals to offer beneficiaries a “preferred provider list” to promote better care and patient experience. At a minimum, hospitals should be permitted to exclude from the list certain post-acute providers with objectively poor quality scores.

Eliminate, or alternatively, streamline all CMMI or CMS-led bundled program beneficiary notices into one standardized notice that could be provided to all Medicare beneficiaries upon admission.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Do not repeal or modify the Stark law or its implementing regulations to expand self-referral to physician-owned hospitals

Summary:

Conflicts of interest are inherent in arrangements whereby physicians refer their patients to hospitals in which they have an ownership interest. After a decade of studies and congressional hearings showing the adverse impact of self-referral to physician-owned hospitals, Congress acted to protect the Medicare and Medicaid programs and the taxpayers that fund them by imposing a prospective ban on self-referral to new physician-owned hospital. The physician self-referral law also places significant restrictions on expansion of existing physician-owned hospitals.

Repealing this prospective ban or loosening these restrictions would lead to over utilization and higher health care costs, while harming patients, community hospitals and local businesses. A recent analysis by the health care economics consulting firm Dobson|DaVanvo compared the performance of non-physician owned full-service community hospitals with physician-owned hospitals, and found that physician-owned hospitals:

- cherry-pick patients by avoiding Medicaid and uninsured patients;
- treat fewer medically complex patients;
- enjoy all-payer margins nearly three times those of non-physician owned hospitals;
- provide few emergency services – an important community benefit; and
- are penalized for unnecessary readmissions at 10 times the rate of non-physician owned hospitals.

It is clear that self-referral to physician-owned hospitals results in cherry-picking of the healthiest and wealthiest patients, excessive utilization of care, and patient safety concerns. Existing law should continue to protect patients, businesses and taxpayers, and help ensure that full-service hospitals can continue to meet their mission to provide quality care to all the patients in their communities.

Related Statute/Regulation:

42 U.S.C. 1395nn(d)(3)(D) and (i)
42 CFR 411.362

Proposed Solution:

Do not repeal or modify the current Stark law or its implementing regulations to expand self-referral to physician-owned hospitals.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Restore excess 0.7 percent ATRA hospital cut

Summary:

In the FY 2018 Medicare Inpatient Prospective Payment System final rule, CMS applied an improper, permanent 0.7 percentage point negative adjustment to the base payment amount. CMS's policy misinterprets the relevant statutory authority under the *Medicare Access and CHIP Reauthorization Act* (MACRA), which explicitly assumes that the *American Taxpayer Relief Act* (ATRA) Section 631 recoupment would result in an estimated 3.2 percent adjustment in FY 2017 and requires that adjustments in a particular year not apply to subsequent years. In implementing Section 631(b) of ATRA, the Secretary laid out a plan to impose an escalating adjustment for each of the four years based on actuarially projected discharges in each year such that the adjustment in the first year, FY 2014, would equal a -0.8 percent reduction to the standardized amount, escalating by -0.8 percent in each year until the adjustment equaled -3.2 percent in 2017. Clearly, at the time ATRA was passed, both Congress and the Secretary recognized that the ATRA recoupment would end by FY 2018.

Related Statute/Regulation:

82 Fed. Reg. 37990 (Aug. 14, 2017) (ATRA IPPS payment adjustment)
Pub. L. 112-240; Section 631 (ATRA)
Pub. L. 114-10; Section 414 (MACRA)

Proposed Solution:

CMS has, and should exercise, its authority to restore the excess 0.7 adjustment and thereby satisfy MACRA's mandate without perpetuating the ATRA adjustment beyond the savings Congress sought to achieve with MACRA.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Relax rules prohibiting Medicare OPPS payment for relocated off-campus hospital departments, and preserve reasonable payment in non-excepted departments

Summary:

Section 603 of the *Bipartisan Budget Act of 2015* (Section 603) imposes site neutral payment for new, off-campus outpatient provider-based departments (PBDs). CMS's rules, however significantly and unnecessarily narrow the statutory exceptions to Section 603 adopted by Congress. In order to serve effectively their communities, provide high quality care in an appropriate setting, successfully renegotiate favorable lease terms, comply with local building codes, respond to changing community needs, as well as preserve access to high quality care in the aftermath of a natural disaster, hospitals need broad flexibility to relocate excepted PBDs, whether on- or off-campus. The FAH concurs with a majority of the members of Congress who have written to CMS urging that it broadly permit excepted PBDs to relocate, recognizing that relocations may be necessary and appropriate in numerous situations that do not involve the acquisition of physician practices. For example, rural hospitals serve communities spread across larger geographic areas, making off-campus outpatient departments an important avenue to providing services needed by the community in the right location. Hospitals deserve to be paid at a reasonable rate for the critical and high-quality care they provide to Medicare beneficiaries, including care furnished in nonexcepted, off-campus PBDs.

Related Statute/Regulation:

Bipartisan Budget Act of 2015 (Pub. L. 114–74) (Section 603 (Site-neutral law))
42 CFR 419.38 (Prohibited off-campus HOPD relocations)

Proposed payment for services in non-excepted off-campus hospital departments:
82 Fed. Reg. 33558 (Jul. 20, 2017) (CY18 OPPS Proposed Rule)
82 Fed. Reg. 33950 (Jul. 21, 2017) (CY18 PFS Proposed Rule)

Proposed Solution:

At a minimum, a number of broad exceptions are necessary to provide hospitals with the flexibility needed to manage efficiently and appropriately their excepted PBDs and deliver high quality care in a safe location. These include relocations:

- *arising from the expiration of a lease or a landlord's option. This exception is critical to ensuring that hospitals can effectively renegotiate their leases and make prudent business decisions;*

- *from sites with environmental issues, including land erosion or proximity to an earthquake fault line, a flood plain, or toxins; and*
- *based on organic growth and community needs.*

In addition, the payment rate for services provided by non-expected PBDs should not fall below the current 50 percent of the Medicare OPPS rate.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Suspend the overall hospital Star Ratings program, and improve the methodology

Summary:

The Star Ratings goal is to make Medicare quality data more understandable for patients, their families and caregivers to help inform choices among facilities, a laudable goal, but the Star Ratings methodology is seriously flawed and should be suspended.

The Star Ratings are devised from combining 64 quality measures into a single score using a mathematical composite methodology. Not every hospital has enough cases of varying types to be able to report on all 64 measures used in the calculation, and some smaller hospitals may not provide all the services included in the 64 measures. The methodology also over-weights the Patient Safety and Adverse Events Composite (PSI-90) measure, a composite of ten discrete quality measures, many of which also are included as individual measures in the Star Ratings. By overweighting the PSI-90 measure, a hospital's performance on some conditions contributes disproportionately to the overall score. Additionally, the methodology for the Star Ratings tries to place small rural hospitals and large tertiary care hospitals on even footing even though the characteristics of these hospitals are disparate. For example, the CMS methodology for compiling Star Ratings does not account appropriately for the size and complexity of hospitals. In addition, the outcomes measures, such as the readmissions measures, are not sufficiently risk adjusted to reflect sociodemographic differences.

The Star Ratings are overly simplified, and are not able to assist patients in factoring into their choices issues such as proximity to home, post-acute services, transportation, and specific providers who have privileges at the facility. For example, patients may choose a facility based on the specific care they need, and a specific provider who provides that care at a specific facility, but the overall Star Ratings do not facilitate that choice. The Star Ratings cannot capture performance on specific services nor hospital capacity and thus do not account for instances in which the care across departments within a facility may not be consistent or when facilities specialize in particular services. Patient's need this type of specific information to make an informed choice of a facility.

Related Statute/Regulation:

78 Fed. Reg. 50776-50778 (August 19, 2013)

Proposed Solution:

Congress should direct CMS to suspend the current Star Ratings program and convene an expert panel and engage further public discussion to:

- *Review the variation in ratings between hospitals with very few reported measures compared to hospitals with a large number of reported measures;*
- *Assess the risk adjustment of individual measures; and*
- *Assess the effect of sociodemographic adjustment for outcome measures.*

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Streamline the number of measures used for payment and comparative purposes and focus on measures that reflect true differences in care and opportunities for improvement

Summary:

Hospitals long have supported the value of quality reporting and were instrumental in beginning voluntary reporting of quality measures nearly 20 years ago. Hospitals statutorily are required to report quality measures in the Inpatient Quality Reporting Program, Outpatient Quality Reporting Program, Hospital Acquired Condition Reduction Program, Hospital Value-Base Purchasing Program, Hospital Readmission Reduction Program, Meaningful Use Program, Outpatient Quality Reporting Program, Long-term Acute Care Quality Reporting Program, Inpatient Rehabilitation Quality Reporting Program, Inpatient Psychiatric Quality Reporting Program, and Inpatient Rehabilitation Quality Reporting Program.

For the Inpatient Quality Reporting program alone, hospitals report more than 90 measures, some of which are relevant for internal quality improvement while others are most relevant for external comparative purposes. The number of measures being reported generally has increased each year, and the proliferation of measures results increasingly in conflict and overlap across programs. Currently, the time lag between delivering care, reporting on the metrics, and receiving feedback on the reported measures is too long. Additionally, current measure sets do not account appropriately for the impact of socioeconomic factors on health care outcomes.

Related Statute/Regulation:

42 U.S.C. 1395 ww(q); 42 CFR 412.152 (Hospital Readmissions)
42 U.S.C. 1395ww(o); 42 CFR 412.167 (Hospital VBP)
42 U.S.C. 1395ww(p); 42 CFR 412.172 (HAC Program)
42 U.S.C. 1395ww(b)(3)(B)(Viii); 42 CFR 412.140 (Hospital IQR)
42 U.S.C. 1395I(t)(17); 42 CFR 419.46 (Hospital OQR)
42 U.S.C. 1395ww(s)(4); 42 CFR 412.432 (Hospital IPFQR)
42 U.S.C 1395ww(m)(5); 42 CFR 412.560 (LTCHQR)
42 U.S.C. 1395ww(j)(7); 42 CFR 412.634 (IRF QRP)
42 U.S.C. 1395ww(n)(3); 42 CFR 495.22; 42 CFR 495.40 (Meaningful Use Quality Reporting)

Proposed Solution:

The federal government should engage in a public process aimed at reducing the number of quality measures used across multiple programs and streamline reporting requirements to provide the most relevant and effective information to assist patients in making decisions

about their care. The FAH recommends assessing the value of each independent quality payment programs and streamlining and appropriately reducing the number of measures used for payment and comparative purposes to reflect true differences in care, opportunities for improvement, and minimization of conflicts across programs. There should be a link between the measure results and the ability of those results to inform improvement in patient care, i.e., the return on the investment for implementing the measure (collecting data, calculating the measure results, using that data to change or improve the care delivered to patients, and receiving fair payment). The FAH urges Congress to direct the HHS to convene a panel to narrow the measure sets to measures that truly make a difference in patient care or address a topic of national significance.

Additionally, Congress should require testing and public reporting of any quality measure before the measure is included in a payment program. Congress should also ensure that outcome measures are appropriately risk adjusted to account for sociodemographic factors that influence patient success. Finally, Congress should direct CMS to expand the programs for which quality vendors are able to submit data on behalf of hospitals (e.g., perinatal care and behavioral health measures). Allowing vendors to electronically submit the data would alleviate data entry burden for hospitals and improve the quality of the data submitted.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Halt AUC implementation and ensure beneficiaries receive timely services

Summary:

Section 1834(q) of the Social Security Act, as added by the *Protecting Access to Medicare Act* (PAMA), established the appropriate use criteria (AUC) program for imaging services. The legislation directed CMS to implement the program in stages: establishing AUC; establishing ways for clinicians to consult with AUC (i.e., clinical decision support mechanisms (CDSMs); requiring consulting with and reporting of AUC by clinicians; and identifying outlier clinicians. There are some exceptions to the program, including ordering imaging for an individual with an emergency medical condition, if the ordering clinician documents the condition that manifested as sufficiently severe to by-pass the AUC process.

In the CY2018 Physician Fee Schedule Proposed Rule, CMS delayed the implementation date for ordering clinicians to consult with specified AUC – and for furnishing clinicians to submit claims-based documentation – until January 1, 2019. Clinicians can begin voluntarily consulting and reporting in July 2018 pending readiness of CMS claims processing systems. CMS also proposed the development of new codes for the furnishing clinician to report the consultation information on the claim form. While the FAH supports CMS’s decision to delay the implementation until January 1, 2019, our members remain concerned that the program is overly burdensome with limited potential benefit in its present form.

Related Statute/Regulation:

42 U.S.C. 1395m(q)

42 CFR 414.94

82 Fed. Reg. 34091-34096 (July 21, 2017)

Proposed Solution:

Congress should direct CMS to indefinitely pause and reevaluate the AUC program to ensure that it is focused on the goal of helping clinicians with decision-making rather than resulting in a “check-the-box” exercise.

In the absence of an overarching “pause” on the program, at a minimum, Congress should direct CMS to further delay the implementation date, paired with a real test period, as opposed to a voluntary reporting period that will begin too soon and end too quickly. The new codes and modifiers CMS discusses in the Proposed Rule will take time to develop and for providers to add to their coding and billing systems.

Additionally, Congress should direct CMS to exclude emergency departments from the AUC program entirely. As currently constructed, the emergency exclusion is burdensome and will divert precious time away from treating the patient during an emergency. Congress should also direct CMS to require that the CDSMs provide the necessary billing codes/modifiers to the clinician consulting the AUC. This will significantly ease the burden on providers of converting the AUC results for billing/reporting purposes.

Finally, Congress should modify the AUC policy so any payment reductions or restrictions are associated with the ordering physician instead of the furnishing provider to ensure it is the ordering physician who is incentivized/required to consult CDSMs. The current requirement to deny payment to the furnishing provider penalizes the furnishing provider rather than the ordering provider and will likely impact beneficiary access. At a minimum, Congress should direct CMS to develop a pathway for a furnishing provider to perform and receive reimbursement for advanced imaging when the ordering physician either does not consult CDSM or does not properly record that consultation. This is essential to ensure that beneficiaries receive necessary, timely services.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Re-evaluate the effectiveness of the EHR Meaningful Use Program, and modify data-blocking attestations by meaningful users of EHR technology

Summary:

Meaningful Use Stage 3

The current Meaningful Use Program is costly and burdensome for providers and has not resulted in the desired efficiencies and patient care improvements. While the recent flexibilities finalized by CMS in the Inpatient Prospective Payment System (IPPS) Final Rule (e.g., 90-day reporting period for CY2018; flexibility to use either the 2015 Edition CEHRT or the 2014 Edition CEHRT; flexibility to attest to either Stage 3 or Modified Stage 2) are helpful to hospitals in complying with the Program, they will not solve the underlying issues of extensive cost and burden yet lack of interoperability. These flexibilities also do not address the lack of alignment of the hospital Meaningful Use Program requirements with the Advancing Care Information (ACI) category of the Merit-Based Incentive Payment System (MIPS), the latter of which removed the “all-or-nothing” requirements for reporting clinicians.

Information Blocking Attestations

Effective April 16, 2016, the *Medicare Access and CHIP Reauthorization Act (MACRA)* requires that “meaningful users” demonstrate that they have not “knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified electronic health record (EHR) technology.” CMS requires this be met through a three-part attestation that is so broad that providers could inadvertently be labeled as “data blockers” for taking reasonable actions regarding EHR functionality in response to requests for medical records.

Related Statute/Regulation:

Meaningful Use:

42 U.S.C. 1395f(1)(3), 1395w-4(o), 1395w-23, 1395ww(n) (Medicare)

42 U.S.C. 1396b (Medicaid)

42 CFR 495.4; 42 CFR 495.22; 42 CFR 495.24; 42 CFR 495.40; 42 CFR 495.60

81 Fed. Reg. 77199-77245 (November 4, 2016) (ACI performance category of the MIPS)

Information blocking:

42 U.S.C. 1395ww(n)(3)(A)(ii) (EHR Hospitals)

42 U.S.C. 1395w-4(o)(2)(A)(ii) (EHR Professionals)

42 CFR 495.40(a)(2)(i)(I) and (b)(2)(i)(I)
81 Fed. Reg. 77028-77035 (November 4, 2016)

Proposed Solution:

Meaningful Use Stage 3

The FAH recommends re-evaluating the Meaningful Use Program, particularly the move to Stage 3, to allow for a meaningful evaluation of whether the Program is meeting its goals and to further align the hospital Program with the ACI category of the MIPS for physicians, including eliminating the “all-or-nothing” standard. At a minimum, a 90-day reporting period is needed in any year in which Stage 3 is first implemented – with appropriate and timely notice to affected stakeholders to enable providers to implement system updates and train staff. These solutions can be achieved through regulation or legislation.

Information Blocking Attestations

The FAH recommends modifications to the MACRA data-blocking attestations to narrow their scope. The FAH also recommends the CMS provide clear guidance on how these requirements will be enforced so that providers understand what actions they need to take and/or avoid in order to be found in compliance. These solutions can be achieved through regulation or legislation.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Expand coverage of and establish payment parity for telehealth services

Summary:

CMS currently engages in an outdated process for determining which services provided via telehealth are eligible for Medicare reimbursement. While CMS could use its authority more broadly, the Medicare statute treats the delivery of services via telehealth too narrowly. These factors have resulted in Medicare beneficiaries not having access to appropriate telehealth services.

Related Statute/Regulation:

42 U.S.C. 1395m(m)

42 CFR 410.78

Proposed Solution:

- *Medical and behavioral health services that can be appropriately delivered via telehealth technology should be reimbursed by Medicare and other payers at the same level as when those services are delivered in person*
- *Support efforts for providers to participate in multi-state telehealth programs*
- *Originating site restrictions should be updated continually as new technologies develop, with the goal of eliminating originating site restrictions in order to make telehealth services available to patients where most convenient for them*
- *Access for telehealth services should not be restricted by geography, and all patients, whether in rural, suburban or urban areas, should be able to avail themselves of medical and behavioral health services via telehealth*
- *Reimbursement should not discriminate based on the technology used and should encourage the use of real-time secure bi-directional audio and video, home health monitoring technologies, store-and-forward technologies, and other synchronous, asynchronous, and remote monitoring technologies*
- *The federal government should take steps to remove Medicare's restrictions and expand reimbursement of telehealth services, and ensure they conform to the above principles.*

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Allow IRFs to carry more risk in bundling programs, while rescinding the 60 percent and three-hour rules

Summary:

Bundled payment programs should encourage high quality patient outcomes through incentivizing more collaborative and coordinated decision-making around the efficient utilization of care and services, including post-acute care (PAC) services. Optimal efficiencies for PAC utilization requires involvement of PAC providers in bundling arrangements. For example, inpatient rehabilitation facilities (IRFs) could test a CMMI bundling program that would not be derived from the IRF prospective payment system (PPS), but instead would permit IRFs to assume the risk of caring for certain patients over a defined period of time and with sufficient regulatory relief, such as rescinding the 60 percent rule and three-hour rule. Bundled payment and delivery programs require hospitals and other providers to be more accountable for their referral decisions for post-acute care services, including both outcomes and spending. These shifting dynamics have obviated the need for stringent rules, such as the 60 percent and three-hour rules. Acute-care hospitals and physicians should have broader flexibility to discharge their patients to the most appropriate level of post-acute care needed to meet their patients' needs. Their decision-making should be influenced by what is best for the patient, and not by whether a patient's diagnosis satisfies the 60 percent rule. Permitting greater shared accountability between hospitals and IRFs would strengthen their relationship and reduce costs by enabling IRFs to pass along savings from accepting payments lower than the IRF discharge-based PPS.

Further, the three-hour rule undermines patient-centered care, especially in a bundled payment and coordinated care environment. This intensive therapy requirement should be aligned with the IRF patient's unique medical and therapy needs and rehabilitation physicians' and therapists' clinical judgment, rather than a cookie cutter approach. Flexibility is needed to address patient need, while ensuring the quality of care and cost efficiencies needed for success in a bundled payment program.

Related Statute/Regulation:

42 U.S.C. 1395ww(j) (IRF payment system)
42 CFR 412.29 (IRF 60 percent and three-hour rules)

Proposed Solution:

Allow IRFs to carry more risk in bundling programs, while rescinding the 60 percent and three-hour rules. Alternatively, at a minimum, IRFs should have the flexibility to provide

three hours of therapy through multiple modes, including group and concurrent therapies, without the risk of Medicare contractors denying the claim for an insufficient amount of “one-on-one” therapy.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Retire the LTCH 25 percent rule

Summary:

CMS should completely retire the 25 Percent Rule as it is no longer necessary in light of the new two-tiered payment system. The new long-term care hospital (LTCH) patient criteria and two-tiered payment system address the same policy concern that the 25 Percent Rule was initially developed to address: that patients may have been transferred to the LTCH setting to maximize reimbursement and not because the LTCH was the most appropriate care setting. Now that payment at the LTCH PPS standard Federal payment rate is only available for a subset of historic LTCH patients with LTCH approved, very specific conditions, the 25 Percent Rule is no longer necessary.

Further, it is arbitrary for CMS to pay for care rendered to LTCH-appropriate patients at different rates (e.g., LTCH rate or IPPS equivalent rate) solely based on the number of patients discharged to the LTCH from the discharging hospital. If the patient is appropriately treated and classified such that the LTCH is eligible for reimbursement at the LTCH PPS standard Federal payment rate, the patient's care should be paid as such, regardless of the percentage of discharges to the LTCH from the discharging or transferring hospital.

Related Statute/Regulation:

42 CFR 412.536

Proposed Solution:

CMS should retire the LTCH 25 percent rule.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Freeze LTCH site neutral blended payment rate

Summary:

The *Pathway for SGR Reform Act*, signed into law in December 2013, established patient and facility criteria governing payment for patients admitted to a long-term care hospital (LTCH). Beginning with cost reporting periods on or after October 1, 2015, payment for patients who do not qualify under the LTCH PPS are based on a “site neutral” rate, which is the lower of either the comparable inpatient prospective payment system per diem rate, including outlier payments, or service costs. The site neutral payment rate is phased in so that, for cost reports beginning in FYs 2016 and 2017, cases are paid a blended rate of 50 percent of the comparable IPPS payment and 50 percent of the payment rate that would otherwise be in effect under the LTCH PPS. For FY 2018 and later, the blended payment rate ends, and payment would be based fully on the site neutral payment rate. FAH is concerned that the site neutral rate is inadequate in light of data indicating the medical complexity and higher acuity as well as the longer length of stays of these patients treated in an LTCH compared to similar patients cared for in a short-stay hospital. As a result, access to LTCH care for these medically complex patients could be compromised.

Related Statute/Regulation:

42 U.S.C. 1395ww(m)(6)

Proposed Solution:

Freeze LTCH site neutral rate at the blended rate.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Refrain from finalizing the proposed Home Health Grouping Model

Summary:

Under its CY 2018 Home Health Prospective Payment System Proposed Rule, CMS would implement in 2019 an untested, new prospective payment system called the Home Health Grouping Model (HHGM). This substantially different payment system has the potential to disrupt patient access to home health care as well as ongoing efforts to transform health care delivery. Moreover, instead of following precedent and adopting a budget neutral approach to implementation, CMS proposes a dramatic reduction in payment associated with this new payment scheme, which could reach \$950 million in its first year.

Related Statute/Regulation:

82 Fed. Reg. 35270 (July 28, 2017)

Proposed Solution:

CMS should refrain from finalizing the HHGM in the CY 2018 Home Health PPS, and at a minimum implement any changes in a budget neutral manner.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Improve the Stark Law

Summary:

Signature Requirement

The FAH supports and appreciates CMS's 2015 revisions to regulations implementing the Stark physician self-referral law (Stark Law) that clarify and simplify temporary noncompliance with signature requirements under existing regulations. Yet, Congress should take further action to modify the signature requirement, and should establish that clear assent between the parties to the terms of the arrangement is sufficient to meet the Stark law signature requirement. As evidenced by recent CMS regulatory action that allowed for indefinite contractual holdovers, CMS itself has effectively acknowledged that, in certain situations, where the terms of an arrangement are clearly outlined, all that is required to continue the arrangement is the clear assent of the parties. Congress should consider adopting this approach in place of the current signature requirement.

In the event that Congress or CMS does not modify the signature requirement, as outlined above, at a minimum, the limitation on the number of times a hospital may use the late signature rule, established by CMS in 2015, should be removed. Currently, CMS allows use of the temporary noncompliance signature rule to once every three years per referring physician, yet, Congress should direct unlimited use of this provision. The temporary noncompliance signature rule does not provide any additional protection from fraud and abuse. To the contrary, it could lead to the type of unnecessary disclosures to the Stark self-disclosure protocol that are contributing to the current backlog and that Congress and CMS are currently seeking to prevent.

Commercially Reasonable Standard

Certain exceptions under the Stark Law utilize several standards to qualify for that exception. Three primary standards used in Stark exceptions require that remuneration under an arrangement: is consistent with fair market value; does not take into account the volume or value of referrals; and, is commercially reasonable. The fair market value and volume or value of referrals standards generally are well understood and can be objectively determined. If payments to physicians are fair market value and do not take into account the volume or value of referrals, these two standards should satisfy the purposes of the Stark Law. The commercially reasonable standard, however, is vague and not generally well understood or objectively measured.

In addition, the commercially reasonable standard also may impede the development of new alternative payment models (APMs). These newer models are highly complex, especially

considering the shared savings and gainsharing arrangements between hospitals and physicians and other downstream providers that must be undertaken for the model to be implemented effectively. Attempting to apply a vague and poorly understood standard such as commercial reasonableness to these newer models creates more uncertainty and is a significant barrier that threatens to chill development and implementation of these new models. The commercially reasonable standard is at odds with the public policy priorities that CMS has articulated.

Overall, the commercially reasonable standard creates substantial uncertainty. The law would be strengthened if this standard were removed, with the more objective and understandable standards of fair market value and volume or value or referrals remaining.

Expedited Self-Referral Disclosure Protocol (SRDP) Review Process

Hospitals expend significant resources and time to resolve Stark Law self-disclosures. They also face financial uncertainty, even after submitting the self-disclosure, as they await their turn in the CMS self-disclosure back log. Consequently, hospitals support the concept of an expedited SRDP review process, and specifically a review process that does not impose harsh, disproportionate financial penalties on the disclosing provider, especially for “technical noncompliance.” Yet, to date, no official action has been taken by CMS. An expedited process would streamline further the existing self-disclosure process (thereby lessening the financial burden and uncertainty within the provider community), and the current backlog of CMS self-disclosures would be reduced.

Related Statute/Regulation:

42 U.S.C. 1395nn; 42 CFR Part 411 (Stark law and related regulations)

42 CFR 411.353(g) (temporary noncompliance with signature requirements)

Proposed Solution:

Congress should establish that clear assent between the parties to the terms of the arrangement is sufficient to meet the Stark law signature requirement. At a minimum, Congress should remove the current limitation on the number of times a hospital may use the late signature rule (as established by CMS in 2015).

Remove the commercially reasonable standard from the Stark Law, with the more objective and understandable standards of fair market value and volume or value or referrals remaining.

Congress should establish an expedited SRDP review process for violations of the Stark law, including for Stark law “technical noncompliance.”

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Create an alternative, and more appropriate, penalty structure for hospitals that inadvertently incur “technical noncompliance” with the Stark Law

Summary:

Currently, hospitals face millions of dollars in penalties for unintended “technical noncompliance” with the Stark physician self-referral law (Stark Law), such as a missing signature on an arrangement that otherwise would pass muster under the law. These technical violations would not pose any risk of Medicare program abuse or overutilization. Yet, the financial uncertainty due to these technically noncompliant arrangements breeds instability when hospitals need the stability and capacity to treat their patients. Further, the delayed time and resources that hospitals spend in resolving Stark self-disclosures of technically noncompliant arrangements creates a cooling effect for hospital integration that is necessary to provide more efficient, better integrated quality care to patients, while curbing the cost curve. Streamlining this process and reducing the existing backlog of self-disclosures also would allow CMS more time and resources to pursue real fraud that actually hurts patients and the Medicare program.

Related Statute/Regulation:

42 U.S.C. 1395nn (Stark law)

Proposed Solution:

Create an alternative, and more appropriate, penalty structure for hospitals that inadvertently incur “technical noncompliance” with the Stark Law to streamline the Stark Law self-disclosure process and help reduce the current backlog of self-disclosures.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Create single bundled payment program waiver of the Stark Law and Medicare AKS

Summary:

Outdated laws and regulations, such as the Stark physician self-referral law (Stark Law) and Medicare anti-kickback statute (AKS), undermine hospital efforts to achieve successful coordinated care arrangements and participate in new APMs. Gainsharing is a critical component of APMs, such as CJR (or the EPM bundled payment programs, should it be implemented), and serves to align participating providers' otherwise disparate financial interests. Yet, to facilitate such gainsharing arrangements, hospitals need legal certainty that such efforts will not run afoul of federal fraud and abuse laws, and an overarching waiver from these laws would provide that certainty and in a timely manner. Gainsharing programs take careful deliberation on the part of numerous stakeholders, involve painstaking drafting of sharing arrangements, and further entail drawn out negotiations with potential gainsharing partners. An overarching waiver, rather than issuance of waivers with a final rule, would allow participants the time needed to enter into effective gainsharing arrangements.

Related Statute/Regulation:

42 U.S.C. 1395nn; 42 CFR Part 411 (Stark law and related regulations)

42 U.S.C. 1320a-7b(b) (Medicare anti-kickback statute)

Proposed Solution:

CMS's current piecemeal approach to bundled payment program fraud and abuse waivers should be replaced with a single, overarching "Bundled Payment Waiver" of the Stark Law and AKS, applicable to all gainsharing arrangements under a CMS-led bundled payment program. Alternatively, a new "Bundled Payment Program Exception" to the Stark law should be considered, or modification of the current Stark law exceptions (e.g., risk-sharing exception) to permit gainsharing under CMS-led bundled payment programs. These recommendations could be accomplished through statute or regulation.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Reform the Medicare RAC program, the Medicare appeals process, and reduce the existing appeals backlog

Summary:

The current Recovery Audit Contractor (RAC) program design, in which RACs receive a contingency fee based on their claim denials, has resulted in overzealous denials, delayed payments to health care providers for appropriate services, and a years-long backlog of appeals, which also creates significant administrative burden for the Medicare program, providers and patients. There are numerous approaches for improving the Medicare appeals process and reducing the current appeals backlog, and our recommendations are bulleted in the solution section below.

See attached Appendix B for further discussion of these recommendations.

Related Statute/Regulation:

42 U.S.C. 1395ff; 1395ff(d)(1)(A) (ALJ appeals review and backlog)
80 Fed. Reg. 70,298 (Nov. 13, 2015) (QIO referrals to RACs)
42 U.S.C. 1395ddd(h) (RACs)
42 U.S.C. 1395ddd(h)(1) (RAC contingency fee)
82 Fed. Reg. 4974 (Jan. 17, 2017) (Medicare appeals process final rule)
42 U.S.C. 1395ddd (f)(2) (Hospital appeals recoupment limitations)

Proposed Solution:

To improve the Medicare appeals process and reduce the current backlog, CMS could –

- *Offer a voluntary claims settlement process*
- *Delay QIO referrals to RACs by one year*
- *Limit scope of RAC/QIO review*
- *Delay RAC payment and recoupment until after ALJ level*
- *Require Medicare contractors to address technicalities before denying a claim*
- *Require physician review of Medicare contractor patient status and medical necessity reviews*
- *Prohibit RAC/QIO denials upon missed deadlines*
- *Penalize RACs for high denial overturn rate*
- *Require transparency of QIO/Medicare contractor claims review standards and guidelines, audit protocols and audit tools*
- *Require contractor transparency for rationale of claims denials*

- *Require robust MAC claims review*
- *Require more education for MAC appeals/allow option to begin appeal at QIC level*
- *Provide Incentives for MACs to resolve appeals*
- *Extend timeframe for hospital appeals recoupment to allow time to develop and submit a more robust and complete appeal, which could result in better outcomes at lower levels of appeal*
- *Consolidate Medicare contractor appeals*
- *Revise and monitor the January 2017 Medicare appeals process final rule.*

Additionally, Congress should eliminate the RAC contingency fee structure.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Simplify and eliminate certain burdensome Medicare provider enrollment processes

Summary:

CMS issued a *Program Integrity Enhancements to Provider Enrollment Process* proposed rule in 2016 to implement statutory requirements to help ensure that entities and individuals who pose risks to the Medicare program and beneficiaries are kept out of or removed from Medicare for extended periods. Under the proposal, a provider or supplier that submits a Medicare, Medicaid, or CHIP enrollment or revalidation application must disclose any current or previous “affiliation,” whether direct or indirect, with a provider or supplier that has had one of four specifically enumerated adverse “disclosable events.” In implementing this statutory provision, the proposed rule is much too broad, unworkable, and unduly burdensome. For example, under the proposed rule, in addition to reporting information about its indirect owners (as currently required), providers and suppliers internally would need to identify all affiliation relationships held by the applicant’s indirect owners, which could include large mutual or pension funds or retirement vehicles that have extremely large and diverse investment holdings, and then determine whether any of these “affiliations” are with a provider or supplier that has had a disclosable event. As ownership in health care providers and suppliers has become more complex and indirect, and increasingly non-health care entities are investing in health care solely as passive investment vehicles, compliance with this requirement will be extremely challenging, if not impossible. It also is highly questionable whether the provisions in the proposed rule would achieve the desired result of reducing fraud, waste, or abuse in federal health care programs.

A separate issue regarding provider enrollment stems from the existing requirement that publicly-traded companies report any direct or indirect ownership interests held by mutual funds or other large investment or stock-holding vehicles on CMS Form 855. Since the ownership percentage of mutual funds or other large investment vehicles in publicly-traded companies may fluctuate daily, thereby rising above or below the five percent reporting threshold, it is unreasonable and burdensome for publicly-traded providers or suppliers to track and report such changes. In addition, the ability of publicly-traded providers or suppliers to gather necessary information to report these mutual fund or other large investment vehicles is oftentimes unreasonably difficult, if not impossible.

Related Statute/Regulation:

81 Fed. Reg. 10720 (Mar. 1, 2016) (Provider enrollment process)
42 CFR 424.510 (Medicare enrollment application)
Medicare Enrollment Application, Institutional Providers CMS-855A

Proposed Solution:

Withdraw the “Program Integrity Enhancements to the Provider Enrollment Process” proposed rule and reconsider a more narrow, tailored approach.

Simplify Medicare enrollment reporting requirements for publicly-traded companies.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Repeal IPAB

Summary:

The Independent Payment Advisory Board (IPAB) is a fifteen-member board appointed by the President, which is charged with making recommendations to cut Medicare expenditures if spending growth reaches an arbitrary level. Once the Secretary of Health and Human Services (HHS) implements an IPAB recommendation, that action is not subject to administrative or judicial review, thus empowering an unelected board without adequate oversight or accountability to take actions historically reserved for elected representatives in the U.S. House and Senate. Absent action by IPAB, the law transfers IPAB's responsibilities solely to the HHS Secretary, an unelected individual. In sum, IPAB represents an unacceptable infringement on the decision-making responsibilities and prerogatives of the Congress.

Related Statute/Regulation:

42 U.S.C. 1395kkk

Proposed Solution:

Congress should repeal IPAB.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Halt payment changes for x-rays taken using CR technology

Summary:

Section 502 of the *Consolidated Appropriations Act, 2016* (Pub. L. 114–113) contains provisions to incentivize the transition from traditional x-ray imaging to digital radiography by limiting payment for film x-ray and computed radiography (CR) imaging services. Specifically, the payment for x-rays taken using film and furnished during CY 2017 or a subsequent year will be reduced by 20 percent; payments for imaging services using computed radiography technology will be reduced by 7 percent if furnished during CY 2018-2022 and by 10 percent if furnished during CY 2023 or a subsequent year.

Related Statute/Regulation:

42 U.S.C. 1395I(t)(16)(F)

Proposed Solution:

The FAH supports the transition away from film-based x-ray equipment, which is antiquated, cumbersome, and costly to both patient and provider. Further, the quality of film-based imaging is much less consistent with what is needed for patient diagnosis.

However, the transition from CR technology to digital and the associated reimbursement cut is overly burdensome. There is insufficient evidence in significant clinical outcomes to warrant the capital requirements to replace equipment when useful life remains on CR equipment. We recommend that Congress allow for this migration to occur organically through the normal life-cycle management of existing CR equipment rather than add additional costs to the health care system. Specifically, Congress should remove the payment provisions associated with the transition from CR technology to digital. Alternatively, Congress should change the effective date of the payment reductions to several years in the future to allow for the normal life-cycle management of existing CR equipment.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Revise the public posting of breaches of unsecured PHI

Summary:

Section 13402(e)(4) of the *Health Information Technology for Economic and Clinical Health* (HITECH Act) requires the Secretary of HHS to post a list of breaches of unsecured protected health information (PHI) affecting 500 or more individuals by entities covered the *Health Insurance Portability and Accountability Act* (HIPAA). The Office for Civil Rights (OCR) has implemented this provision via the HIPAA Breach Reporting Tool (HBRT), which makes available to the public information about the breach, including: name and location of the entity; date of the breach; type of breach (e.g., theft, loss, hacking/IT); location of the breached information (e.g., paper records, laptop); and number of affected individuals.

Once a breach is posted on the website, it is never removed, regardless of whether the provider has resolved any security issues or was a victim of hacking or ransomware despite having appropriate cybersecurity safeguards. The HBRT was recently revised such that recent or unresolved breaches are listed under one display and older/resolved breaches are listed under the “archive” tab. However, breaches are never removed from the website. Additionally, current public notifications about a breach do not include consumer-friendly information on the level of risk associated with the breach, which can lead to confusion among consumers.

Related Statute/Regulation:

42 U.S.C. 17932
45 CFR Part 164

Proposed Solution:

To improve the accuracy of reporting cyber-related breaches to the public and continue building a security partnership with the industry, FAH recommends the creation of a mechanism for HHS to remove organizations from the breach reporting website. A breach of healthcare information does not necessarily mean that an organization has poor security. There should be an exception to the public listing (or otherwise limit the listing to a minimal period) for organizations that were subject to cyberattacks or other crimes despite having appropriate safeguards. If such organizations are listed on the website for a limited time, there should be a clearer description on the website indicating that they were compliant with all security protocols at the time of the breach. For organizations that did have security issues, their names should be removed from the list if they can demonstrate that they have resolved those issues and implemented appropriate information security tools and protocols.

Additionally, the FAH encourages HHS to continue to build a security partnership with the industry, rather than take a punitive approach. Specifically, the FAH recommends an approach focused on assistance to organizations in protecting PHI rather than publicizing entities that have suffered security breaches irrespective of the circumstances of the breach.

Lastly, any public notification about a breach should include information allowing consumers to properly gauge the level of risk associated with the information breach. This assessment could be based on existing risk assessment factors under 45 CFR 164.402 (2)i-iv, which include the types of identifiers and likelihood of reidentification, the unauthorized person who used the PHI or to whom the disclosure was made, whether the PHI was actually acquired or viewed, and the extent to which the risk to PHI has been mitigated.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Reform HIPAA requirements to establish cybersecurity safe harbors and clarify guidelines regarding requests for protected health information

Summary:

Cybersecurity Safe Harbors

The *Health Insurance Portability and Accountability Act of 1996* (HIPAA) Security Rule requires “covered entities,” such as health care providers, to address and assess cybersecurity risks, so that they can safeguard the confidentiality and security of electronic protected health information (PHI). Providers also are audited to ensure compliance with these requirements. Failure to comply with HIPAA can result in substantial monetary penalties, even when providers are the victims of a cyber-attack despite investing in and practicing good cyber readiness and risk management.

Requests for PHI

HIPAA permits a “covered entity” to impose a reasonable, cost-based fee to provide the individual (or the individual’s personal representative) with a copy of the individual’s PHI, or to direct the copy to a designated third party. There is substantial confusion, however, regarding these fees. While guidelines issued by the Office for Civil Rights (OCR) in February 2016 were intended to clarify matters, much confusion remains, especially regarding fees that may be charged for “third party” requests for this information, such as requests for massive amounts of medical records/PHI requested for litigation purposes.

Related Statute/Regulation:

42 U.S.C. 1320d through 1320d-6
45 CFR 160; 45 CFR 164, Subparts A and C (Security Rule)
45 CFR 164.524 (Access of individuals to PHI)

Proposed Solution:

Cybersecurity

The FAH recommends the development of safe harbors for providers that demonstrate a minimum level of cyberattack readiness and mature information risk management programs. The FAH also recommends positive incentives for providers meeting these safe harbors rather than the current punitive approach.

Requests for PHI

The FAH recommends that OCR be required to work with affected stakeholders to develop clear guidelines regarding “covered entity” fees and processes that may be charged for individuals’ PHI, and distinguish third party requests for PHI versus requests from individuals or their personal representative.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Reform MA requirements to relieve burdens on providers and ensure patient access to care

Summary:

Compliance Training Requirements

CMS recently implemented new Medicare Advantage (MA) compliance training requirements for hospitals and other first tier, downstream, and related entities (FDRs) based on use of standardized and more generic training modules developed by CMS. Hospitals take compliance training very seriously, and over many years have developed sophisticated compliance programs designed to meet federal compliance training requirements, while using their own internal comprehensive and personalized compliance training programs that are very specific to the compliance protocols in a specific hospital. While CMS has taken steps to provide hospitals with some flexibility in being able to integrate their own compliance training materials with the CMS modules, these modules continue to cause unnecessary burden and confusion for hospital employees. For example, CMS modules often impose training requirements that are not relevant to a particular hospital, and results in training being offered out of context or in a disjointed manner that is not clear and concise. Further, CMS has been issuing new compliance training requirements for a coming year after the year has started, while many hospital systems that provide thousands of employees with compliance training, have developed and rolled out their compliance training programs well before the start of the year.

Readmissions Penalties

Medicare Advantage Organizations (MAOs) make use of CMS reimbursement methodology and its constituent parts to determine reimbursement rates to providers for a variety of services. CMS integrates several factors into its determination of reimbursement rates for inpatient services in the CMS PC Pricer, including whether a hospital has experienced excessive readmissions relative to a standard established under the Hospital Readmissions Reduction Program (HRRP). An analog of the CMS PC Pricer through purchased software is used by MAO plans to make payments to contracted hospital providers for inpatient hospital services.

The HRRP has succeeded in lowering the readmission rate – an ASPE study published in the New England Journal of Medicine reports that readmissions have dropped significantly overall, and hospital inpatient care under traditional Medicare is not simply being converted to outpatient stays. The incentives created by the HRRP have successfully encouraged hospitals to improve quality of care and their communications to post-acute providers, positively impacting readmission statistics.

The HRRP, as designed, does not result in the denial of coverage for a readmission. Rather it imposes a financial penalty for excessive readmissions on every admission. MAO plans not only use that penalty through the analog of the CMS PC Pricer to reduce payments to hospitals, but they are denying patient readmissions post discharge. This is occurring in some instances whether the readmission was related or unrelated to the prior admission. Our hospital members report that the level of such denials for readmissions have risen dramatically. MAOs are running claim edits to determine whether a prior admission had occurred within thirty days of a current admission, and denying payment for the current admission without any investigation as to the medical necessity for the current admission. Thus, MAOs apply the HRRP reduction, but do not follow the HRRP policy. In this regard, the MAOs generate a significant financial shift by penalizing hospitals twice.

Network Adequacy at the Sub-Network-Level

Beneficiaries often do not have accurate lists of the providers available to them both at the time they choose a plan and when they need to choose a provider. Additionally, beneficiaries receive less coverage than they expect when there are material changes to an MAO's network of providers during the plan year, or if they cannot access the identified network of providers after they have enrolled. Our members have witnessed firsthand during the last several years the confusion that enrollees often experience when navigating provider networks and the challenges they can face when their access to care is restricted. CMS's "Online Provider Directory Report," released January 13, 2017, documents many of the inaccuracies in MAO directories and the inability of beneficiaries to get appointments with many MAO providers.

An MAO's apparent compliance with network adequacy standards may obscure issues with actual network adequacy and the scope of represented provider options to enrollees within the network, if the MAO uses downstream organizations to provide administrative and health care services to beneficiaries. Downstream organizations are often affiliated with their own contracted or employed physician or provider groups, and the sub-capitation arrangements create a financial motivation for downstream organizations to direct care to a particular physician or provider group. As a result, these provider groups often become the enrollees' de facto provider network.

Unfortunately, network adequacy looks at the whole network a plan identifies, not to the sub-network to which many enrollees are relegated. These "networks within a network" are often far narrower than the provider network depicted in the provider directory or the Health Service Delivery (HSD) tables on which CMS based its approval of an MAO, thus creating a more narrow network as the beneficiary moves through the healthcare continuum. Enrollees may have selected a particular MAO plan on the basis of its provider network, only to realize later that a downstream organization will discourage enrollees from accessing particular providers. This is especially problematic when a hospital is identified as in-network in the provider directory, but the physicians affiliated with the hospital, while in the main network, are not a part of the physician or provider group to which the downstream organization directs enrollees. Moreover, the downstream organization's sub-network may not meet the network adequacy standards to which the MAO is subject.

Network Adequacy for Post-Acute Care

A provider's identification in a network directory does not necessarily mean the provider truly is available. Our MA patients experience the situation where a patient stay no longer meets the standards of care for inpatient services, but there are no medically appropriate post-acute settings available for discharge. This occurs because the MAO has no additional financial cost to extend a patient's hospital length-of-stay under the MS-DRG system, but would have additional cost if they transferred the patient to the appropriate post-acute provider of care. Patients have a right under the Medicare Act to be treated in an appropriate environment, and this includes a discharge from the inpatient hospital setting when appropriate.

Further, current CMS network adequacy standards do not include inpatient rehabilitation facilities (IRFs) as a provider type that requires a specific number or threshold for the provider network and many MAOs have extremely high denial rates for IRF services. To the extent that post-acute care services are available, these factors result in MAOs providing rehabilitation services almost exclusively in skilled nursing facilities (SNFs), which we do not believe meets the requirement that MA plans offer "equal" benefits as are provided under traditional fee-for-service Medicare.

Provider Contract Terminations

While CMS has reexamined its guidance on provider contract terminations in response to significant mid-year changes to MAO provider networks, CMS could do more to ensure adequate notice and transparency for beneficiaries and providers regarding MAO provider contract terminations.

Significant terminations – even those that continue to meet CMS Health Service Delivery (HSD) and benefit requirements – are always going to be accompanied by disruption and may call into questions the MAO's ability to actually deliver the benefits to which it attests in the submission of its plan benefit package(s). For example, after an MAO terminates a provider contract, it is unclear whether the MAO continues to meet network adequacy standards. This information is currently not made available to the public, which can lead to confusion for beneficiaries and their providers when, for example, a major physician practice is suddenly terminated from the network. Additionally, beneficiaries can receive notices of termination that are still being appealed by the provider or receive notices right before the Annual Enrollment Period (AEP).

Related Statute/Regulation:

Compliance Training Requirements:

42 CFR 422.503(b)(4)(vi)(C)(3); 42 CFR 423.504(b)(4)(vi)(C)(4)

Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual (Pub. 100-16; Pub. 100-18) (January 11, 2013)

<https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c21.pdf>

CMS HPMS memo, *Additional Guidance – Compliance Program Training Requirements and Audit Process Update* (February 10, 2016) <https://www.cms.gov/Medicare/Compliance-and->

[Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2016 Compliance and - FWA Training Requirement Update.pdf](#)

CMS HPMS memo, *Update-Reducing the Burden of the Compliance Program Training Requirements* (June 17, 2015) <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/Update Reducing Burden CP Training-Requirements.pdf>

Readmission Penalties:

42 CFR Part 422 (Medicare Advantage)

Network Adequacy:

42 CFR 422.254(a)(4) (meaningful difference)

42 CFR 422.112(a)(1) (provider network)

2018 final Call Letter at p. 116 (April 3, 2017) <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf>

CMS Online Provider Directory Report (January 13, 2017)

https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Final_01-13-17.pdf

Medicare Advantage Network Adequacy Guidance (Last updated: January 10, 2017)

https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/Downloads/MA_Network_Adequacy_Criteria_Guidance_Document_1-10-17.pdf

Provider Contract Terminations:

42 CFR 422.202(d) (suspension or termination of contract)

42 CFR 422.112(a)(1) (provider network)

2015 final Call Letter pgs. 103, 105, 107 (April 7, 2014) <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2015.pdf>

Chapter 4 of the Medicare Managed Care Manual (Issued April 22, 2016)

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf>

Proposed Solution:

Compliance Training Requirements

CMS should streamline the MA compliance training requirements for FDRs, including hospitals, and exempt FDRs from using the CMS compliance training programs if the FDR has an internal, comprehensive compliance training program that includes training similar to the CMS training.

Readmission Penalties

CMS should issue guidance directing MAOs to either following their own readmission policies that hospitals will accept or dispute and eliminate the HRRP penalties from their payment

calculation through their analog PC Pricer, or follow HRRP and its related policies concerning readmissions and cease all denials of all-cause readmissions.

Network Adequacy at the Sub-Network Level

CMS should target network adequacy problems in audits of MAO provider networks to ensure that enrollees can access the benefits to which they are entitled. CMS should also include a standard in the Star Rating System to promote the adequacy and stability of an MAO's network. Additionally, CMS should adopt specific requirements for MAO provider directories and use the audit protocols to ensure that these directories accurately depict the true scope of the provider network. In particular, MAO provider directories should include information regarding in-network physicians' medical groups and institutional affiliations. This level of detail would allow CMS to identify and address the incongruities created by the use of downstream organizations while allowing beneficiaries to make informed plan selections.

Network Adequacy for Post-Acute Care

CMS should consider for purposes of network adequacy that MAOs demonstrate meaningful access, including a review of availability of listed post-acute providers that are accepting MA patients. Additionally, CMS should audit MAO practices associated with approving timely discharges to an appropriate post-acute care setting.

CMS should also ensure that IRF coverage is equally available to MAO enrollees as is available to fee-for-service beneficiaries, and specifically consider requiring MAOs to report denial rates by provider type.

Provider Contract Terminations

To address network adequacy concerns, lack of transparency, provide timely notification, and ensure beneficiary protections related to contract terminations, CMS should:

- *Require that MAOs be transparent regarding the specific metrics that formed the basis to terminate a provider, thus allowing the provider to thoroughly understand the reason for termination, and allowing for an appeal and possible cure over a specified timeframe. CMS should collect this information as part of the documentation CMS currently collects from MAOs during the provider contract termination process.*
- *Reevaluate network adequacy after an MAO provider contract termination and make public that information. At a minimum, that information should be provided in response to requests from health care providers and beneficiaries.*
- *Implement beneficiary protections, including no less than 60-days notice to beneficiaries of provider terminations so that they can exercise their choices, including a right to revert to traditional Medicare or to select another MAO plan. MAOs should also be required to maintain the current beneficiary cost sharing for the out-of-network providers during a transition period.*
- *Require no less than 60-days notice to providers of contract terminations.*
- *Require that, but for exceptional circumstances, plans be prohibited from undertaking notice to providers of terminations during certain periods.*

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Delay the Transition from SSNs to MBIs

Summary:

The transition from using Social Security Numbers (SSNs) to Medicare Beneficiary Identifiers (MBIs) is an enormous undertaking for the Medicare program, the states, beneficiaries, and the providers who serve them. Congress put forth an aggressive timeline for this transition in the *Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)*, requiring these changes by April 2019. However, given the current state of implementation planning, it is unlikely CMS can meet this deadline without severe consequences for stakeholders, including interruptions in beneficiary access to care. Thus far, stakeholders have raised concerns regarding state readiness; interactions with Medicare Advantage reporting; beneficiary and provider education; the vulnerability of the cards to fraud, especially as millions of new cards are mailed to beneficiaries; and the need for a longer transition period in which both SSNs and MBIs will be accepted. We commend CMS for setting up a mailbox for stakeholders to submit their questions; however, there have been limited responses from the Agency to those questions, and stakeholders do not believe they have enough time to complete the necessary system changes and training.

Related Statute/Regulation:

42 U.S.C. 405(c)(2)(C)

Proposed Solution:

The numerous stakeholder timing, operational, and fraud concerns call for CMS and/or Congress to delay the transition to MBIs in order to address these concerns and prevent negative consequences for beneficiaries. The Agency should use the additional time to provide the necessary clarifications and education to providers and beneficiaries.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Ensure appropriate pre-deployment testing of all federal systems for collecting and reporting of hospital quality data at CMS the CDC

Summary:

Data systems used to collect and report quality measurement data are complex and sometimes antiquated, and upgrades to systems are not fully tested before deployment, causing delays or suspension of public reporting.

Hospitals are required to report quality measures to both CMS and CDC on a regular periodic basis. While the Ways and Means Committee does not have CDC within its jurisdiction, the measures reported to CDC are used in federal hospital payment programs under the jurisdiction of the Committee. As such, the Committee should be aware that the data systems upgrades often are faulty and not fully tested before being deployed. For instance, CMS had to recall hospital preview reports, suspend public reporting of infection measures, or change reporting deadlines three times in the first quarter of 2017 due to problems with the QualityNet reporting system and the CDC's National Healthcare Safety Network.

Related Statute/Regulation:

42 U.S.C. 1395ww(b)(3)(B)(viii) (inpatient quality reporting)

42 U.S.C. 1395l(t)(17) (outpatient quality reporting)

Proposed Solution:

Both CMS and CDC should be required to undertake more robust testing of the data collection systems, including beta-testing teams of participating hospitals and facilities to test submissions and retrievals using current patient data, prior to the full roll-out of any upgrades. More robust pre-deployment system testing would ensure quality data was recorded correctly and that the systems could accurately calculate the measure results prior to full deployment.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

Postpone all *Improving Medicare Post-Acute Care Transformation Act of 2014* (IMPACT Act) quality measure implementation until the new cross-cutting measures have been tested and refined in the specific settings where the measures are being used

Summary:

The IMPACT Act requires post-acute providers to report quality measures to CMS and CDC. However, measure specifications are not aligned across the various post-acute settings, which creates confusion for providers. Additionally, data is not well-specified when collected and does not adequately capture the care provided in the specific setting. The varying complexity of patients and their care needs across post-acute settings challenges measure developers to effectively capture true differences in patient care; developers are working with CMS to refine measures and to ensure accurate comparable data can be captured across care settings.

Related Statute/Regulation:

42 U.S.C. 1395III (IMPACT Act)
42 CFR 412.634 (IRF QRP)
42 CFR 412.560 (LTCHQR)

Proposed Solution:

Congress should direct CMS to postpone all IMPACT Act quality measure implementation until the new cross-cutting quality measures have been tested and refined in the specific setting where they will be used.

Medicare Red Tape Relief Project
Committee on Ways and Means, Subcommittee on Health

Short Description:

The CMS Survey and Certification process should retain flexibility for private sector accreditors to innovate while still meeting or exceeding CMS survey standards

Summary:

The Department of Health and Human Services has historically deemed that providers meeting certain private sector accrediting body standards (e.g., the Joint Commission) meet or exceed the Medicare Conditions of Participation (CoPs). Recently, the Agency has begun requiring these private sector bodies to use the same survey processes used by CMS. Such restrictions limit variation and innovation in the private sector.

For example, CMS has recently taken a more restrictive approach to shared medical space (co-location), which has caused confusion and infeasible surveyor requirements, such as imposing requirements that a shared space be separate from the hospital and provide, for example, an independent entrance and waiting areas. Hospitals often share medical space with other providers because it allows them to furnish a broader range of services tailored toward the health needs of their patients. Such arrangements are especially important for providing patients with greater access to care, including in rural areas where specialists can travel to a rural hospital to treat patients. Also, for post-acute care providers, the ability to co-locate with a hospital is becoming increasingly important as payment and care delivery models continue to be developed throughout the country. The recent CMS restrictions present significant obstacles for patient access and quality of care, as well as moving toward more value-based care.

Related Statute/Regulation:

42 CFR 401

42 CFR 488

42 CFR 489

Proposed Solution:

Congress should direct CMS to retain flexibility for private sector accreditors to create innovative improvement programs and work directly with their clients on reforming internal hospital systems to improve facility management and meet or exceed the minimum required by federal regulations. For example, Congress should direct CMS to promptly issue flexible guidelines regarding co-location arrangements to allow greater access to care and enhance coordinated care for patients.