Making Federal Regulation Less Burdensome
A Discussion on ASA Regulatory Advocacy

Matthew T. Popovich
Director, Quality and Regulatory Affairs
The Wisconsin Society of Anesthesiologists
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Disclosures

Matt Popovich works at the American Society of Anesthesiologists.

Quality and Regulatory Affairs (QRA)

Two Staff in Washington, DC – Two Staff in Schaumburg, IL

Matt Popovich, Ph.D.
Director

Toni Kaye, MPH
Quality Program Manager
* Measure Analysis
* Measure Testing
* Nat’l Measure Reviews

Beth Quill, J.D.
Senior Regulatory Specialist
* Anesthesia Department Administration
* HealthIT and EHR regulation

Leslie Kociemba, MPH
Senior Quality Associate
* QPP Policy and Analysis
* Regulatory Advocacy
* Education Materials

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Quality and Regulatory Affairs (QRA)

Unfortunately, not a Wisconsin department.

Objectives

• “Regulatory Burden” has become a catchphrase for the current administration. Learn how the American Society of Anesthesiologists (ASA) is engaging federal stakeholders on this topic and what that may mean for your individual practice.
• Understand how there are different interpretations of “regulatory relief.”
• Learn how recent “regulatory relief” changes to the Merit-based Incentive Payment System (MIPS) may affect your bottom line.
Section 1: Regulation Under the Current Administration

Administrations often use a simple framework or motto to guide their regulatory decision making.

Obama Administration

Trump Administration

ASA communicates with Executive Office agencies in a number of ways:

Face-to-Face Meetings

Coalitions and Comments

* American Medical Association
* Surgical Coalition
* Drug shortage coalitions
* Pain medicine coalitions
Patients Over Paperwork

Initiative 1: Patients Over Paperwork

CMS Goals Include:
1. Reduce unnecessary burden and cost
2. Increase efficiencies
3. Improve the beneficiary experience

Dr. Seema Verma, CMS Administrator: Patients over paperwork is aimed at reducing “Regulations that are not contributing to patient safety, quality or program integrity but instead are only increasing our healthcare costs.”

Patients Over Paperwork

Initiative 1: Patients Over Paperwork

CMS policy Implications:
1. Increased minimum threshold for participation in MIPS
2. Hardship Exemptions for QPP Promoting Interoperability
3. Evaluation and Management Code Revisions
4. Simplification of office visit documentation (e.g., teaching physicians may verify student’s E&M visit notes)
5. Stark Law and Anti-Kickback Regulations
Patients Over Paperwork - Successes

In 2017, ASA physicians and regulatory staff directly offered these solutions for anesthesiologists:

1. Reducing PQRS requirements for 2016 (payment year 2018) – SUCCESS
2. Eliminating negative Value-Based Payment Modifier for 2018 – SUCCESS
3. Removal of subjective pain questions from CAHPS surveys – SUCCESS
4. Greater ASA participation in FDA and other regulatory panels that address the opioid crisis – SUCCESS

Patients Over Paperwork – More to Do

ASA physician leaders and multiple ASA departments are working to reduce your burden via the Patients Over Paperwork initiative.

1. Petitioning for removal of oxytocin from the NIOSH Hazardous Drug List
2. Working with TJC and CMS to reduce administrative burdens to workflows
3. Opt-In for anesthesiologists wishing to report MIPS
4. Work on increasing anesthesiologist presence in rural and underserved areas via Rural Pass through legislation and regulation

Meaningful Measures

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Meaningful Measures

Initiative 2: Meaningful Measures

CMS Goals Include:
1. Promote alignment across quality initiatives and programs to minimize burden
2. Promote focused quality measure development toward outcomes that are meaningful to patients, families and providers
3. Identify highest priorities in improving healthcare
4. Assess how CMS delivers value – better care, smarter spending, healthier communities (Question: Sound Familiar?)

Meaningful Measures

Objectives for the meaningful measures framework include:
- Address measure areas that safeguard public health
- Patient-centered and meaningful to patients
- Outcome-based where possible
- Fulfill each program’s statutory requirements
- Minimize documentation burdens
- Significant opportunity for improvement
- Address population-based payment through alternative payment models
- Align across programs
CMS Meaningful Measures Policy	Impact to Anesthesiologists

Must safeguard public health	Limited, mostly to opioids
Be patient-centered and meaningful to patients and their caregivers	Limited, mostly patient satisfaction and experience and patient safety
Should be outcomes-based	Attribution issues and long-term outcomes are difficult for individual anesthesiologists to assess
Must fulfill statutory requirements	MIPS requirements for six measures

Minimize documentation burdens	Emphasis on electronic health records; discouraging check-box measures.
Opportunity for improvement	50% of measures are “topped out” – anesthesiology measures more than other specialties.
Population-based payment through alternative payment models	Need to demonstrate how anesthesia measures contribute to long-term outcomes and lower costs.
Align across programs	Anesthesia measures mostly MIPS only

Initiative 2: Meaningful Measures

CMS Policy Implications:
1. Proposed removal of 34 quality measures in QPP/MIPS (limit claims-based measures to small practices only)
2. Proposed removal of transfer of care measures (MIPS 426 and MIPS 427)
3. Increasingly difficult for CMS to recognize anesthesia measures as meaningful to patients (few outcome measures, attribution issues)
4. Difficulty having new measures approved by CMS
Meaningful Measures – More to Do

ASA physician leaders, QRA and the Anesthesia Quality Institute are working to reduce your burden and ensure practices have every opportunity to report meaningful anesthesia quality measures.

1. Arguing for continued recognition by CMS of MIPS 426 and MIPS 427 in MIPS
2. Lobbying that the use of “topped out” measures should continue until a better process for measure approval is implemented by CMS
3. Developing perioperative and sub-specialty quality measures in AQA NACOR
4. Having CMS recognize that not every measure can be e-specified (need options for registry reporting)

Regulatory Change Framed as Burden Reduction

Section 1 Takeaways:

• Regulatory burden reduction is a serious initiative that includes CMS and other agencies making hard decisions and implementing change.
• Patients Over Paperwork is another term for removing unnecessary or duplicative regulatory and billing requirements.
• Meaningful Measures is a term used to expeditiously remove quality measures from multiple CMS programs.
  o Meaningful Measures program has been used in a positive sense as well.
Section 2: Regulatory Change and Your Practice

Two case studies:
1. Participation in the Quality Payment Program (QPP)
2. Quality measure development for anesthesiologists and qualified anesthesia providers

Participation in the Quality Payment Program (QPP)

CASE STUDY #1
Quality Payment Program (QPP) pathways:
- Merit-based Incentive Payment System (MIPS)
  - Eligible clinicians and groups receive positive, neutral or negative payment adjustments
- Advanced Alternative Payment Models (Advanced APM)
  - Potential for 5% bonus for up to 6 years, depending on thresholds and definition

Understanding MACRA Regulatory Requirements

<table>
<thead>
<tr>
<th>Payment Year</th>
<th>Performance Categories (Reweighting Possible)</th>
<th>MIPS Adjustment Factor (+/-)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quality</td>
<td>Cost</td>
</tr>
<tr>
<td>2020</td>
<td>50%</td>
<td>10%</td>
</tr>
<tr>
<td>2021</td>
<td>30%</td>
<td>30%</td>
</tr>
<tr>
<td>2022 and Beyond</td>
<td>30%</td>
<td>30%</td>
</tr>
</tbody>
</table>
**MIPS Adjustment Factor**

<table>
<thead>
<tr>
<th>Points</th>
<th>Adjustment on Medicare Part B Covered Professional Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0 – 3.75</td>
<td>Negative: 0%</td>
</tr>
<tr>
<td>3.76 – 14.99</td>
<td>Negative: Greater than -5% to less than 0% on a linear sliding scale</td>
</tr>
<tr>
<td>15.00</td>
<td>Neutral</td>
</tr>
<tr>
<td>15.01 – 69.99</td>
<td>Positive: Greater than 0% to 5% on a linear sliding scale</td>
</tr>
<tr>
<td>70.00 – 100.00</td>
<td>Positive: Greater than 0% to 5% on a linear sliding scale</td>
</tr>
</tbody>
</table>

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**Participation in the Quality Payment Program (QPP)**

**Example 1: Application of the MIPS Participation Threshold**

CMS removed physicians and others from MIPS via minimum payment and/or patients thresholds citing “burden reduction.”

- $90,000 in Medicare covered professional services **AND** 200 Medicare Patients
- CMS (2018 Final Rule): “We believe that increasing the number of such individual eligible clinicians and groups excluded from MIPS participation would reduce burden and mitigate, to the extent feasible, the issue surrounding confounding variables impacting performance under the MIPS.”

**Alternative Take Away:** If you can’t play, you can’t receive a positive payment adjustment.

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**Participation in the Quality Payment Program (QPP)**

**Example 2: Application of the MIPS Quality Component**

CMS established the MIPS Quality Data completeness threshold at 60% of all applicable cases as part of “reducing burden”.

- CMS (2018 Proposed Rule): “The data completeness threshold of less than 100 percent is intended to reduce burden and accommodate operational issues that may arise during data collection during the initial years of the program.
- Anesthesiology Measure Set **OR** Qualified Clinical Data Registry Measures
- Reporting less than 60% of your cases still gives a practice points, just not as many.

**Alternative Take Away:** A “Catch-22” - if you implement the system correctly, data submission should be easy; if you need to implement data collection and reporting, it’s a burden.
Participation in the Quality Payment Program (QPP)

CMS has proposed to retire six Promoting Interoperability measures as part of burden reduction in 2019:
- Measures to be removed were: 1) and 2) Request/Accept Summary of Care and Clinical Information Reconciliation; 3) Patient-Specific Education; 4) Secure Messaging; 5) View, Download, or Transmit; 6) and Patient-Generated Health Data.
- Data showed ECs had difficulty reporting these measures.
- Physicians did not have much control over the measures.

Alternative Take Away: CMS was aware of challenges in collecting these measures; anesthesiologists typically don’t report Promoting Interoperability measures.

Example 3: Application of the MIPS Promoting Interoperability Component

Practices Will See Both Benefits and Drawbacks to “Burden Reduction.”
1. Burden reduction is often based on evidence and feedback.
2. Not all burden reduction will have a positive impact on your practice.
   - Identify your primary and secondary interests (workflow, investment, etc.).
   - Does the regulation affect my practice?
   - Is the burden administrative, clinical or interdisciplinary?
3. Approach burden reduction cautiously!
   - CMS rarely explains whose burden is being reduced – yours or CMS’s?
   - Regulation needs to be deliberate and thoughtful (e.g., E/M documentation).

Need a Break?
Quality Measure Development

CASE STUDY #2

Developing quality measures

• Anesthesiologists use data for Medicare, payers and other reasons (e.g., contracts, improvement).

• Quality measures must be based upon guidelines and scientific evidence. Measures must be tested and validated.

• The inability to collect and report quality measures may impact contracts, payment and ideals of collective responsibility.

A quality measure consists of at least a denominator and a numerator.

• Denominator: A statement that describes the population evaluated by the quality measure
  o Often includes CPT® Codes, ICD-10 codes or other patient population elements (age, condition, anesthesia type)

• Numerator: A statement of the measure’s target process, procedure, clinical action or outcome
  o The upper part of the fraction used to calculate a percentage or ratio

What is a “Quality Measure”?

This is what I’m saying:

3 (numerator)

4 (denominator)
Federal legislation and regulation over the past 20 years have allowed for the proliferation of quality measures.

**Federal legislation on Eligible Professionals / Eligible Clinicians**
- PQRS in 2006 under TRHCA (penalties under ACA, budget neutral)
- EHRs in 2009 under HITECH Act part of ARRA (stimulus)
- VM in 2010 under ACA (budget neutral with PQRS)
- MACRA in 2017

**Federal legislation on Hospitals/Facilities**
- HVBP in 2003 under Medicare Prescription Drug Act
- EHRs in 2009 under HITECH Act part of ARRA (stimulus)
- Ambulatory Surgery Center Quality Reporting or "ASCQR" Program has legislative history dating to the last century

The Meaningful Measures initiative transcends multiple features of quality measure use, policy, rules and regulations.

- CMS Measures Inventory
  - 26 programs that use quality measures
  - 1,950 quality measures in use or under development
- CMS Measures Management System Blueprint (Vol. 13.0)
- CMS Quality Strategy
- MACRA Measure Development Plan (Updated Annually)
- Proposed and Final Rules

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Quality Measure Development

ASA continues to improve our measure development cycle and to critically assess member needs vs. federal policy.

- Advocate on the uniqueness of anesthesia care and measurement.
- Critically assess of quality measures in federal programs.
  - Reality check - Anesthesia measures are topped out, they need to be appropriately linked to outcomes and must have room for improvement.
- Encourage practices to submit a wider array of data to AQI.
  - Build measures on immediate outcomes, patient satisfaction and patient-reported outcomes.

“Burden reduction” does not mean the same thing for all specialties, payers and other stakeholders.

- Anesthesiology workflows mean something
- High performance should not be penalized (removal of measures, avoidance of key drivers of patient outcomes)
- CMS must allow anesthesiologists to compete fairly in payment programs

Recap

Section 1: Regulation Under the Current Administration
- Patients Over Paperwork
- Meaningful Measures

Section 2: Regulatory Change and Your Practice
- Quality Payment Program
- Quality Measure Development
Recap – Objectives

• “Regulatory Burden” has become a catchphrase for the current administration. Learn how the American Society of Anesthesiologists (ASA) is engaging federal stakeholders on this topic and what that may mean for your individual practice.
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Questions / Comments

Matthew T. Popovich (m.popovich@asahq.org)
Director, ASA Quality and Regulatory Affairs

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Quality and Regulatory Affairs (qra@asahq.org)

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