Advocacy Council
Regulatory “Alphabet Soup” Update – ACA, ACO, APM’s, MACRA

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1. Disclosure & Acknowledgements

- Speaker for MEDA
- HIPAA
- Acknowledge contributions of Advocacy Council Members & Staff in preparing this talk:
Objectives

• Discuss the new payment models and understand how other regulatory changes are impacting allergy practice.

• List options to avoid Medicare penalties in 2019

• Define APM
Challenges We Face Today and in 2017

- ICD-10 & other Coding Issues
- Restrictions on 95165
- Fall out from Epi-Pen issues
- CMS Medicare Issues
- FDA Insanitary regulations
- USP & Compounding Regulations
- MACRA, MIP’s & APM’s
The Advocacy Council: Who Are We??

• The group formerly known as the JCAAI
  – Transition in 2015
  – Structurally independent
• No longer financially supported by AAAAI
• Board now entirely appointed by ACAAI
• Mission remains the same, bigger focus on local issues
• House of Delegates & Practice Management Committee now under same umbrella
• Staff transitions October 2017
  – James Sublett, MD, now Executive Director, Advocacy and Governmental Affairs
  – Don Aaronson, MD, JD now emeritus status
  – Gary N Gross, MD still contributing in a big way
ICD-10

• Successful October 1, 2015 transition
• CMS one year grace period has ended
  – Adopted by most insurance companies
  – Code must be in same family
• Denied payment non-specific codes ending in “.9”
  – ICD-10 is all about specificity
  – Big issue with auto-coding EMR’s
  – Concern about COPD & GERD with only “.9” codes
  – Some payers may allow non-specific codes outside of your specialty
• Other specified codes ending in “.89”
  – Rhinitis codes for mite, cockroach & mold.
• New allergy ICD-10 codes will become effective October 1
• ICD -11 already in development
  – College active in development
New ICD-10 allergy codes added on October 1, 2016

- D8940  Add  "Mast cell activation, unspecified"
- D8941  Add  Monoclonal mast cell activation syndrome
- D8942  Add  Idiopathic mast cell activation syndrome
- D8943  Add  Secondary mast cell activation
- D8949  Add  Other mast cell activation disorder
- K522   Delete  Allergic and dietetic gastroenteritis and colitis
- K5221  Add  Food protein-induced enterocolitis syndrome
- K5222  Add  Food protein-induced enteropathy
- K5229  Add  Other allergic and dietetic gastroenteritis and colitis
- K9041  Add  Non-celiac gluten sensitivity
- Z053   Add  Observation and evaluation of newborn for suspected respiratory condition ruled out
- Z0543  Add  Observation and evaluation of newborn for suspected immunologic condition ruled out
The “JW” modifier for discarded drugs or biologicals

- Providers are required to use the “JW” modifier on claims to report the unused portion of drugs or biologicals from single-use vials
- Effective January 1, 2017
- This policy mandates that the discarded amount of drugs or biologics be recorded in your patient’s medical record.
- Example
  - a single-use vial of a drug that contains 100 units has 95 units administered to the patient and 5 units discarded
  - The 95-unit dose is billed on one line and the 5 unit discarded dose is billed on a separate line with modifier JW
Restrictions on 95165: Allergy Extracts

• CPT definition - Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)
• Because of increased utilization, third party payers have been putting annual caps on the units, (e.g., 120/90)
• July 2016, Medicare began making public their MUE’s (Medically Unlikely Edits)
  – 95165 is 30
  – Medicare does not follow the CPT definition, instead defines as 1ml
• In at least a dozen states Medicaid and some private payer’s have adopted this number
  – Developed “Talking Points”, Florida Medicaid data
• Cigna nationally has raised the limit to 150 after correspondence from the AC
Fall out from the EpiPen issues

• Pharmaceutical pricing is more complicated than anyone can imagine
• The rise of Bronze plans
  – Huge deductibles
• Focused attention on the politics of adding specific medications to the preventive drug list mandated by the ACA
• Congress &/or the administration could use the EpiPen experience to justify government purchasing/negotiations for drug pricing
  – the ramifications of this not just for EpiPens but all other prescription drugs.
• New Jersey has proposed a law REQUIRING epinephrine self injectors be sold as single units
  – We really DON’T have a free market
• Access to needed drugs
Is your practice due for a Medicare enrollment revalidation?

- Required to revalidate their entire Medicare enrollment record every five years
- Notice two to three months prior to the revalidation due date
- Also check their revalidation due dates online
- Strongly recommend you check this website regularly
  - [https://data.cms.gov/revalidation](https://data.cms.gov/revalidation)
- The fastest and most efficient way to submit your revalidation information is by using Internet-based PECOS
60-Day Medicare repayment rule

- Although the 60-day overpayment rule has been in effect since 2010, there were no implementing regulations until recently.
- The 60-day repayment clock will begin to run only after the provider has identified the overpayment and quantified the amount—so long as the provider exercises reasonable diligence.
- Reasonable diligence includes both proactive compliance activities designed to detect overpayments and reactive investigations designed to quantify overpayments in response to credible information.
- The look back period is six years from receipt of payment.
- This should not be interpreted as legal advice. If you think the overpayment rule may apply to you and your practice, the Advocacy Council (AC) recommends you contact a knowledgeable healthcare attorney.
Patient Relationship Codes & Fingerprinting

- **Patient Relationship Codes**
  - Required by MACRA
  - Will be used with care episode codes & patient condition codes to measure performance
  - AC submitted comments

- **Fingerprinting**
  - ACA requires background checks, including fingerprinting, for so-called “high risk” providers seeking to enroll in the Medicare program
  - Nurse Practitioner in an A/I practice that was subjected to a full background check and fingerprinting that met none of the criteria
  - CMS “corrective action” to local Medicare Contractors
The ACA Nondiscrimination Provisions: Section 1557

• Physicians receiving Medicaid or Meaningful Use payments must comply.
  – By October 16, 2016

• Requirements
  – Post notices, taglines, and take steps to provide meaningful access to individuals with Limited English Proficiency (LEP).
  – May need to enter into a contract with a call center.
  – All covered entities must post notice and taglines in the top 15 languages in the state in a conspicuously visible font size for individuals with LEP.
  – Changes may be coming with new administration
RUC & Proposed Medicare Fee Schedule for 2017

- Venom immunotherapy codes
  - increase 16%-39%
  - AC work in submitting bills
  - Done prior to the current shortage & price increases
- Immunotherapy codes (including 95165)
  - required review
  - Maintained value
- Skin Test Codes 95004
  - required review
  - Considered at October meeting
  - Worked with AAAAI & AAOA
FDA Guidance on Insanitary Conditions at Compounding Facilities

- Comment period ended October 3
- The proposed stringent standards (ISO Class 5 environment) would directly conflict with FDA's Draft Guidance on Mixing, Diluting or Repackaging standards, designed to ensure patients' access to allergenic extract treatment
- All items not meeting standard would be considered “adulterated”
- If adopted, this proposal will adversely affect the ability of allergists to bill for extract preparations
- Requested an exclusion for allergen extracts.
- Impact of new administration?
Alphabet Soup:
MACRA, MIPS and APMs
What is MACRA?

The Medicare Access and CHIP Reauthorization Act (MACRA) was signed into law in April 2015

• Repeals the flawed sustainable growth rate

• Bases payments more on value and quality – and less on volume

• But…. It also shifts financial risk to physicians!
  – Medicare physician payments will be linked to clinical decision making
What’s the goal of MACRA?

• Save money (in the aggregate)
  – Keep patients out of the E/D
  – Keep patients out of the hospital

• Improve clinical outcomes

• Reduce reporting burden (supposedly)
MACRA Payment Options

• Replaces PQRS, Meaningful Use (MU) and Value-Based Modifier (VBM) with a single program called the **Quality Payment Program**.

• The Quality Payment Program provides two Medicare payment choices for clinicians
  
  – **Merit Based Incentive Payment System (MIPS)**
  
  – **Alternative Payment Models (APMs)**
Can I skip MIPS and APMs?

• If you don’t participate in MIPS, you will receive an automatic negative adjustment to Medicare reimbursements
  – 4% in 2019, increasing to 9% in 2022 and beyond

• “But I don’t have many Medicare patients. This won’t affect me.”
  – Commercial payers are now adopting pay-for-performance programs. They will soon be the new norm.

• Our recommendation: unless you will be retiring in the next few years, plan to participate.
MACRA timeline – reporting is just around the corner!

• 2016 is last reporting year for PQRS, meaningful use and value-based payment modifier
  – Payment adjustments for 2016 reporting will occur in 2018

• Reporting for MIPS or APMs begins in 2017!
  – CMS announced flexible reporting options for 2017 that will exempt physicians from penalties
  – Practices that report minimal data in 2017 will avoid a negative payment adjustment in 2019

• MIPS payment adjustments or APM bonuses begin two years later, in 2019
Timeline of Implementation:

- **Fee Schedule**
  - +0.5% each year
  - No change
  - +0.25% or 0.75%

- **Max Adjustment**
  - (+/-)
  - 4, 5, 7, 9, 9, 9, 9

- **First Performance Period starts Jan 1, 2017**

- **QP in Advanced APM**
  - +5% bonus (excluded from MIPS)
MIPS consolidates existing Medicare programs (PQRS, VBM, Meaningful Use) into one composite score. The score is based on performance in four categories:

- Quality (previously PQRS)
- Resource Use (previously part of VBM)
- Advancing Care Information (previously MU)
- Clinical Practice Improvement Activities (new category)

You will receive a positive or negative payment adjustment based on your score.

But MIPS must be budget neutral, so negative adjustments are required to offset positive adjustments. You are competing against other physicians!
# MIPS Category Weights and Potential Adjustments by Year

## MIPS Performance Categories & Weighting

<table>
<thead>
<tr>
<th>Performance Year</th>
<th>Payment Year</th>
<th>Quality</th>
<th>Resource Use</th>
<th>Clinical Improvement Activities</th>
<th>Advancing Care Information</th>
<th>Potential Adjustment</th>
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<td>2017</td>
<td>2019</td>
<td>60%</td>
<td>0%</td>
<td>15%</td>
<td>25%</td>
<td>+/- 4%</td>
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<td>30%</td>
<td>15%</td>
<td>25%</td>
<td>+/- 7%</td>
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<tr>
<td>2020 and beyond</td>
<td>2022 and beyond</td>
<td>30%</td>
<td>30%</td>
<td>15%</td>
<td>25%</td>
<td>+/- 9%</td>
</tr>
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</table>
How will MIPS impact allergists?

• CMS estimates 2,507 (63%) allergists will participate in MIPS
  – 8-15% are projected to receive negative adjustments
  – 85-92% are projected to receive positive or neutral adjustments

• CMS estimates 37% of allergists will be excluded from MIPS
  (32% based on low Medicare volumes and the rest for other reasons).
  – Physicians with less than $30,000 in Medicare claims OR less than 100
    Medicare patients are exempt

• CMS estimates
  – 80%-90% of solo or small practices (1-9 clinicians) of all specialties will
    receive a positive or neutral adjustment.
  – 10%-20% will likely receive MIPS penalties
So, can I get out of reporting by reducing my Medicare exposure?

- The 2017 reporting requirements are based on 2016 patterns
- If you saw over 100 patients, or made more than 30K in 2016, then you must participate or face penalty
- CMS will notify you if you are exempt
- Not too late to impact 2018
- Changes may be coming
2017 data determines payment in 2019

- There has been some confusion. Although the payment adjustments do not begin until 2019, the data that will be used to determine the payment adjustments will be reported in 2017.

- The MACRA law stipulated that reporting shall begin in 2017 but DID NOT stipulate when or how long the reporting must occur in 2017.

- Many organizations, recommended that CMS delay actionable reporting until either Q3 or Q4 of 2017 to give additional time to prepare – and test – the reporting mechanisms.

- And they listened!
Three 2017 MIPS reporting options to avoid Medicare penalties in 2019

• Minimal MIPS Reporting  
  – Report one quality measure OR one improvement activity OR the required EHR measures and avoid a penalty

• Partial MIPS Reporting  
  – Report more than one quality measure OR more than one improvement activity OR more than the required EHR measures for at least 90 days and be eligible for a small bonus payment

• Full MIPS Reporting  
  – Report all measures for at least 90 days and be eligible for a bonus payment

Failure to participate (if required) will result in a 4% penalty.
Is there a better option?
Maybe - **Alternative Payment Models (APMs)**

- Eligible professionals can avoid MIPS if they are deemed participating or partially participating providers in “Advanced” APMs.

- APMs are ways of paying for physician services that are different from the current Physician Fee Schedule

- They require physicians to bear some financial risk for costs and quality of care

- Qualifying AAPM participants receive **annual 5% lump sum bonus** payments from 2019-2024
  - if participants receive 25% of Medicare Part B payments through an Advanced APM or see 20% of Medicare patients through an Advanced APM in 2017 and 2018. Percentages increase for future years.
Advanced APM Requirements

• Participants must bear “more than nominal financial risk”.
  – If APM actual expenditures exceed expected expenditures, CMS would withhold payment, reduce rates, or require the entity to make payments to CMS.

• Participants must meet quality measures comparable to those in MIPS.

• Participants must use certified EHR technology.
Are there current APM options for allergists?

- There are few existing opportunities for independent allergists to participate in Advanced APMs, unless your practice is part of an ACO which participates in one of these programs:
  - The Medicare Shared Savings Program (tracks 2 and 3)
  - Next Generation ACO model
A bright spot: Physician-Focused Payment Models

- The law created a Physician-focused Payment Technical Advisory Committee (PTAC) to review APMs developed by physicians.
- Encourages model development by specialty societies.
- Must still meet Advanced APM criteria – but focus on areas physicians can control and to which they can be held accountable.
Advocacy Council APMs

• The Advocacy Council has an APM committee that is developing APMs for allergists
• We have a draft of an APM for Asthma that is ready for testing
  o In process of identifying pilot practices
  o Practices should have a strong relationship with local major payers
  o Practices should have an EHR
  o Practices should be working with PCPs who are interested/participating in value-based care or with independent practices looking for specialist partners
  o Practices should have an interest in developing payment models for allergists
• Are you interested in learning more? See me for details!
What should you do now to prepare for these changes?

1. Determine whether you are required to participate
   - Do you have less than $30,000 in annual Medicare allowed charges or less than 100 Medicare patients?

2. If you must participate, will you report under MIPS or APM for 2017? Most allergists will report under MIPS.
   - AMA Payment Model Evaluator:  www.ama-payment-model-evaluator.com

3. Continue to learn about MACRA and reporting options
   - CMS Quality Payment Program website https://qpp.cms.gov/
   - Watch for articles in weekly Advocacy Insider emails
   - Access the College’s MACRA overview at college.acaai.org/macra
What should you do now to prepare for these changes?

4. If you are in a small (or solo) practice, how much do you value your autonomy?
   – Is it worth a 9% cut in fees?
   – Evaluate your options moving forward

5. If you don’t have an EHR, it should be part of your short-term strategic plan

6. Free MACRA help is available!
   – Transforming Clinical Practice Initiative (TCPI) will support 140,000+ clinical practices over four years: [http://www.healthcarecommunities.org/CommunityNews/TCPI.aspx](http://www.healthcarecommunities.org/CommunityNews/TCPI.aspx)
We have a new President
What does this mean for -

The future of the Affordable Care Act?
   Tom Price, MD HHS Secretary nominee
The future of MACRA/MIPS?
   Passed with bi-partisan support
Health Policy Direction?
Change is the only thing certain