An Update on the Alphabet Soup of Government Regulation

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Disclosures

- Speaker
  - Pfizer
  - Optinose
- Advisory Board
  - GSK
  - Greer

Political Talk

LEARNING OBJECTIVES

- Evaluate changes that allergy practice will need to make if the currently proposed USP & FDA regulation on mixing allergy extracts are finalized
- Utilize strategies for surviving and thriving in the face of changes in coding and governmental regulation
- Examine challenges we face in providing venom immunotherapy

The Advocacy Council: Who Are We?

- The group formerly know as the JCAAI
  - Transition in 2015
  - Structurally independent
- House of Delegates & Practice Management Committee now under same umbrella
- Staff transitions October 2017
- Current Staff and officers
  - James Sublett, MD - Executive Director, Advocacy and Governmental Affairs
  - Sue Grupe - Director of Advocacy Administration
  - Stephen Imbeau - Chairman
  - Jim Tracy - Vice Chairman
  - Gary N Gross, MD - Consultant still contributing in a big way on coding questions

USP Chapter 797 Update

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- First discovered issue in September 2015
- On Feb. 26, 2018 USP announced their timeline for Chapter 797
  - July 27, 2018: Proposed rule – new Chapter <797> – open for public comments
  - Nov. 30, 2018: Comment period ends
  - June 1, 2019: Intended publication of revised Chapter <797>
  - Dec. 1, 2019: FINAL rule becomes official
- James Sublett & Drew Murphy represented allergy at the most recent USP meetings.

USP
U.S. Pharmacopeial Convention

Key points of the USP Chapter 797 revision

- Allergen extract is restored as a separate section of the proposed chapter.
- Confirmed previous allergen extract compounding requirements
  - Personnel training and evaluation.
  - Hygiene and garbing.
  - Updated documentation requirements.
- Also required either:
  - ISO Class 5, Primary Engineering Control (PEC), OR
  - Dedicated Allergenic Extracts Compounding Area (AECA)

USP: Allergenic Extracts Compounding Area (AECA)

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- The requirements for an AECA include:
  - Dedicated area
  - No carpeting
  - Impervious surfaces
  - No outside doors or openable windows
  - A visible perimeter
  - Additional reasonable expectations for sterile compounding in the physician office
- Documentation requirements for:
  - Compounding procedures
  - Temperature logs for refrigeration
  - Prescription set documentation
- Laminar flow hood was not required

USP U.S. Pharmacopeial Convention

Key points of the USP Chapter 797 revision

- Compounding staff will be required to be trained and regularly evaluated on aseptic and compounding technique (mostly reflecting existing requirements)
- Additional requirements
  - Fingertip testing
  - Thumb sampling
  - Details will be sent by AC when finalized
- BUD (by use date) remains 12 months
- Large compounders may oppose our separate section

FDA Guidance on Insanitary Conditions at Compounding Facilities

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- Comment period ended October 3, 2016
- 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
- Productive in person meetings June 6, 2017 & June 19, 2018.

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FDA

FDA Guidance on Insanitary Conditions at Compounding Facilities

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- September 25, 2018 FDA issued revised draft guidance
- The FDA listened to us and others in the medical community
- The FDA does not intend to enforce the insanitary conditions provision "against a physician who is compounding or repackaging a drug product, or who is mixing, diluting, or repackaging a biological product, provided that such activities occur in the physician's office where the products are administered or dispensed to his own patients."
- FDA considers preparation of biologics (e.g., allergenic extracts) to be "mixing, diluting, or repackaging" rather than compounding
  - Compounding is a term it reserves for "drugs."
  - The word "compounding" is not used with reference to biologics
- This is still a draft guidance document.
  - We have made comments

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CMS Proposed Rule revising the Physician Payment Schedule for 2019

- In the name of burden reduction, CMS is seeking to move documentation standards away from chart entries – done to justify a particular level of E&M payment – to entries relevant to the clinical needs of the patient.
- Compact the current five level payment structure into a two-level system
  - Allergy/immunology would be one of nine specialties to get a “complexity” adjustment of $14.
- Reduce reimbursement for inhalant allergen immunotherapy, 95165
- CMS proposed to implement a payment reduction of 50% on one service when it is provided with another service during the same encounter.
  - Applies primarily to codes with a global period
  - Does not apply to any of the skin testing, spirometry, or Xolair administration codes.

CMS Proposed Rule revising the Physician Payment Schedule for 2019

- In person meetings expressing opposition with AAAAI in August 2018
  - We are concerned about the failure of reimbursement to keep up with the spike in the cost of venom antigens.
  - The CMS proposal to reduce reimbursement for inhalant allergen immunotherapy.
- Wide opposition by most of house of medicine
- Submitted written comments, as individual society, and with others, like the AMA.
- The Advocacy Council contacted each United States Senator *personally*, asking them to sign on to the Cassidy/Brown letter and support withdrawing the consolidation of E&M codes, while offering to work with CMS to develop a different solution.

Example: Office visit – established patient

HCPCS/CPT Code	Current non-facility payment rate	Proposed Medicare non-facility payment rate
99211	$22	$24
99212	$45	$93*
99213	$75	$93*
99214	$109	$93*
99215	$148	$93*

*Allergy/immunology would be one of nine specialties to get a “complexity” adjustment of $14, to $107.

CMS Final Rule revising the Physician Payment Schedule for 2019

- The Advocacy Council's efforts to convince CMS to increase reimbursement for inhalant and venom antigens were successful. For 2019 payments will:
- 95165 (allergy extracts) increase by 8%
- Venom antigens (95145-95149) increase by between 9-12%
- Administration of immunotherapy injections (95115 and 95117) both increase by 4%
- Spirometry (94010) declines by 2%.
- CMS has decided to delay its proposed E&M consolidation until 2021.
- Decrease in reimbursement for skin tests CPT 95004. This is the second year of a two-year phase-in resulting from a revaluation of this code in 2017
- Estimated 1% overall decrease in allergy reimbursement from Medicare.

CMS Final Rule revising the Physician Payment Schedule for 2019

- CMS is not finalizing the multiple payment policy reduction for E&M services on the same day as procedures
- Beginning in 2019, there will be a new prolonged service code where face-to-face time exceeds 34 minutes for established patients and 38 minutes for new patients.
- Also beginning in 2019, physicians will no longer be required to re-record elements of history and physical exam when there is evidence that the information has been reviewed and updated.
- Beginning in 2019, physicians must only document that they reviewed and verified information regarding the chief complaint and history that is already recorded by ancillary staff or the patient.

CMS proposes new rules about interoperability

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- On February 11 2019, CMS issued proposed rules to fulfill statutory requirements in the 21st Century Cures Act.
- Improve the ability of health care providers to transmit patient health information to each other in an interoperable format
- Improve the ability of patients to access their personal electronic health data, and
- Prevent health care systems from engaging in “information blocking.”
- Most proposed to take effect in 2020

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

American College of Allergy, Asthma & Immunology

2018 Strike Force: May 7-8, 2019

- Held in conjunction with AAN Capitol Hill Day
  - Used shared talking points for both groups.
  - Joined by the president & executive vice president of the Academy.
- Appointments with Key decision makers
  - Senate majority leaders staff
  - Congressman Griffiths
  - Congressman Aderholt
  - Special assistant to the president for health policy in the White House Energy & Commerce
  - Rep. Ro Khanna to thank him for taking a leadership role in seeking increased funding for food allergy research
  - Senate HELP committee (which over sees health)
  - Senate Finance Committee
- Focused on, network access issues, surprise billing and the failure of HHS to seriously consider most of the physician-focused payment models
  - Given significant advice


Energy and
Commerce
2123

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 doses
  - Medicare does not follow the CPT definition, instead defines dose as 1ml
  - Does not pay for diluted vials made from the concentrated vial
- Many state Medicaid and some private payer's have adopted this number
  - Webinar on topic https://bit.ly/2KjN187
- Cigna nationally has raised the limit to 150 after correspondence from the AC

Venom Supply Issues

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- ALK announced March 1, 2018 leaving the venom market
  - After October 2016 announcement of supply problems
- Venom Immunotherapy Codes for 2017
  - Increased 16%-39% for 2017
  - AC work in submitting bills
  - Done prior to the current shortage & price increases
- Receipts submitted in 2018 were insufficient to justify additional increases.
  - Still monitoring, and will request change in RVU when justified.
- Venom antigens (95145-95149) increase by between 9-12% for 2019 direct contact with CMS
- Annals publishing a fact based opinion article in 2019
- Joint ACAAI-AAAAI Call with Hollister on May 14, 2018
  - Manufacturing and distribution plans for venom extract for the United States and Canada.
  - Messaging from sales reps to physician offices regarding availability of venom extract
  - Not able to discuss pricing or volume discounts.

American College of Allergy, Asthma & Immunology

Step Therapy & PA Issues

- Advocacy Council joined a coalition that includes several physician and patient organizations in supporting both Federal and state legislation designed to address step therapy issues.
- Ohio has enacted legislation that promises to restrict the ability of insurers to impose unreasonable step therapy requirements.
- Bills are pending in Florida, Georgia, Maine, Massachusetts, New Mexico, Oregon, Rhode Island, Utah and Vermont.
- Close alliance with AfPA
- New Tool Kit on ACAAAI website, partnership with industry
  - https://bit.ly/2Kg5lia
  - Worked closely with AfPA & AAN

College Coding Solutions

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- The College website has resources including a toolkit all about coding, great webinars, and helpful articles, recent examples:
- Coding Toolkit
- Billing, Coding and Your Bottom Line
- Are you billing correctly for nurse practitioners and physician assistants?

How did allergy/immunology fare with MIPS in 2017?

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- A total of 2,969 clinicians in the allergy/immunology specialty were required to participate in MIPS.
  - Approximately 89% participated and 11% did not.
  - Lower than the average participation rate for all clinicians of 94.6%.
- In total, 95% of all clinicians required to participate in MIPS avoided a negative payment adjustment in 2019 based on 2017 performance.
  - 93% earned a positive payment adjustment.
  - 2% avoided a penalty.
- But bonuses were small because the program was required to be budget-neutral.
- Penalties were steep: 5% of all clinicians received penalties ranging from -2.1% to -4.0%.

MIPS Changes in last 18 months

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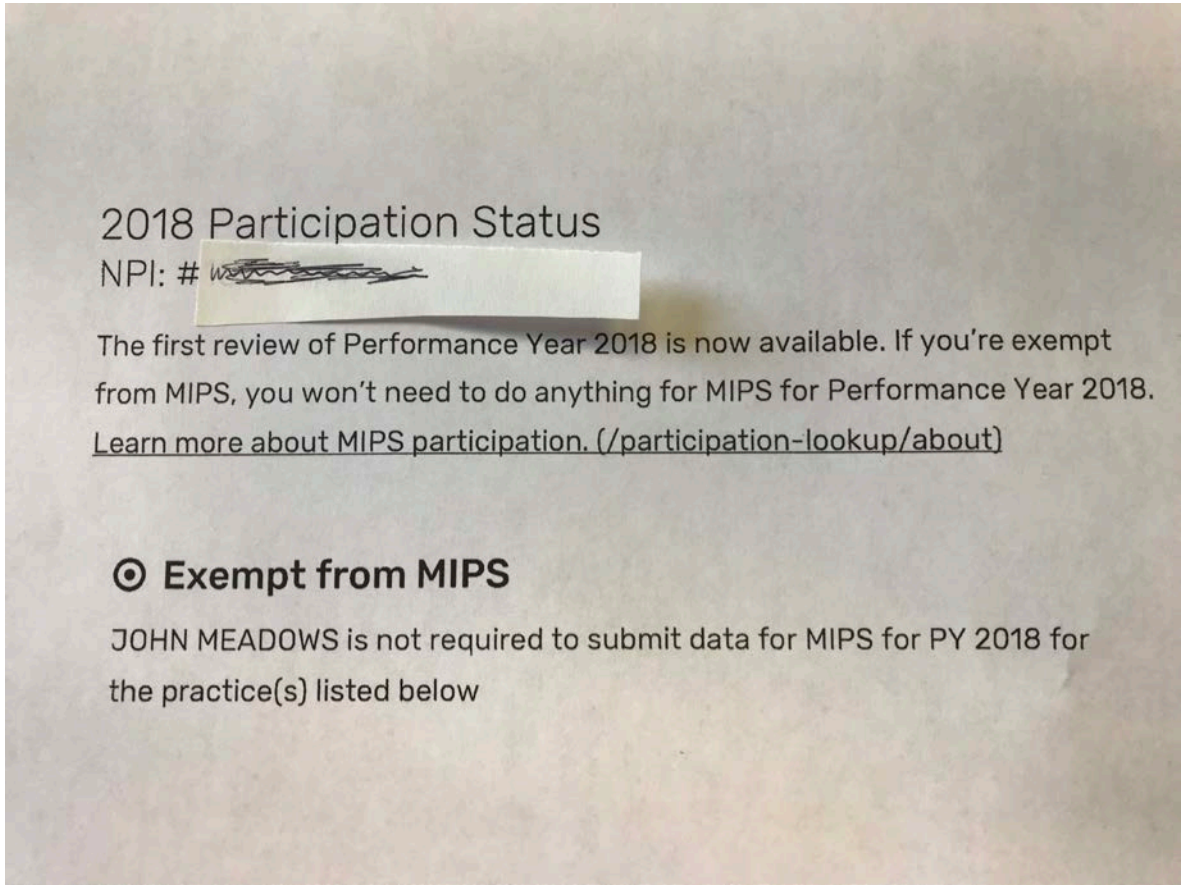
- Announced June 20, 2017
  - Applies to the 2018 performance year & 2020 payment year
- Raises the threshold for participation in MIPS
  - Increases the threshold to exclude clinicians or groups with $90K or less in Medicare charges (was 30K) or 200 or fewer Part B Medicare beneficiaries (was100).
  - AC has advocated for $100K threshold
- Many more allergists will got an exemption in 2018 than did in 2017
- New for 2019 HCQIS Access Roles and Profile (HARP) system.
  - You'll use HARP instead of the Enterprise Identify Management (EIDM) system
  - Reporting MIPS data
  - Checking group MIPS eligibility status
- CMS will notify doctors if they are exempt or not, or you can check
  - Instructions in an insider
  - CMS estimates that only 37% of physicians will be subject to MIPs


2018 Participation Status
NPI: #
The first review of Performance Year 2018 is now available. If you're exempt from MIPS, you won't need to do anything for MIPS for Performance Year 2018.
Learn more about MIPS participation. (/participation-lookup/about)
Exempt from MIPS
JOHN MEADOWS is not required to submit data for MIPS for PY 2018 for the practice(s) listed below

“Next steps for the Merit-based Incentive Payment System (MIPS)”

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- The title of a meeting held by Medicare Payment Advisory Commission (MedPAC) on October 5, 2017
  - MedPAC is an independent US federal body established by the Balanced Budget Act of 1997
  - 17 members bring diverse expertise in the financing and delivery of health care services
- Commissioners are prepared to recommend to Congress that MIPS should be repealed altogether.
  - The significant reporting burden MIPS places on clinicians.
  - The lack of confidence that high performance on MIPS measures actually results in higher value care.
- The MedPAC Commissioners and staff appear to have concluded that MIPS will not achieve its goal of identifying and rewarding high-value clinicians.

“Next steps for the Merit-based Incentive Payment System (MIPS)”

- The proposed “replacement” option has been dubbed the “Voluntary Value Program (VVP)
- The VVP would withhold a percent of all fee schedule reimbursement from clinicians up front and then offer clinicians the chance to earn that money back plus more if clinicians performed well on certain “population-based” measures
- The overwhelming sentiment among the Commissioners was that MedPAC should recommend repealing MIPS, but no formal vote was taken.
- Not certain were that leaves registries designed to meet MACRA regulations
- Still need to participate in 2019

Advocacy Council APMs

- The Advocacy Council has is developed an APM for allergists
- June 2018 Health and Human Services rejected all 12 physician-focused payment models submitted
  - Approved by PTAC
- On the advice of our consultants, we are still submitting our plan to PTAC
- Asthma APM is ready for testing
  - Identifying pilot practices
  - Strong relationship with local major payers
  - EHR
  - Practices are working with PCPs who are interested/participating in value-based care or with independent practices looking for specialist partners