Federal Issues Facing A/I Specialists and Their Patients

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Agenda

- MACRA
  - Year 3 Merit-based Incentive Payment System (MIPS) Proposals
- MedPAC
- 2019 Medicare Physician Fee Schedule (MPFS) Proposals
- Other Key Federal Issues
  - Drug Pricing Blueprint
  - Medicare Advantage and Part D
  - Patients Over Paperwork
  - Drug Compounding
  - Precision Medicine
- What's on deck?

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MACRA

MACRA

QPP

MIPS | APMs

MIPS

Provides payment adjustments based on a composite score across four categories:

- Quality (PQRS)
- Cost (Value Modifier)
- Promoting Interoperability (PI) ("Meaningful Use")
- Improvement Activities (IA)

Advanced APMs

Provides a 5% lump sum incentive payment for clinicians who have significant participation in ***risk-based*** APMs that rely on certified EHR technology and MIPS-like quality measures (aka "Advanced APMs").

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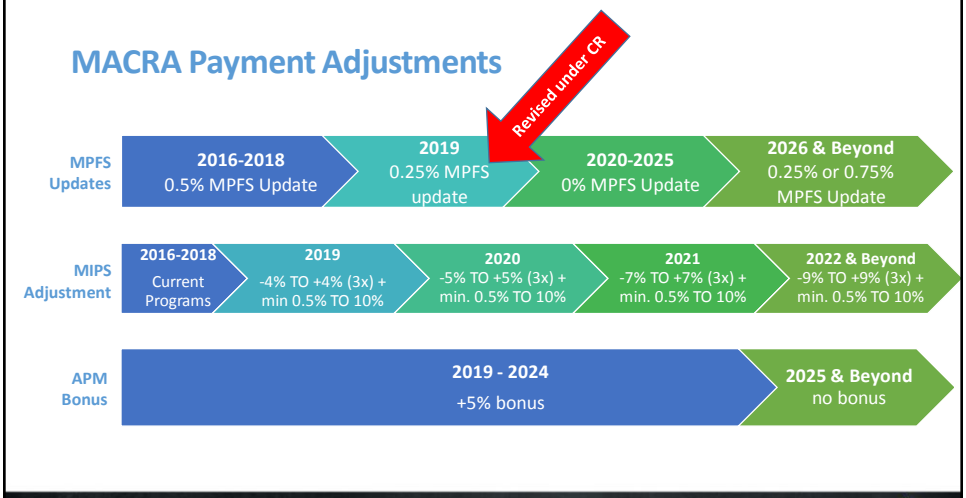
MACRA Payment Adjustments



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MACRA "Technical Changes" in Bipartisan Budget Act (BBA) of 2018

- **Excludes Medicare Part B drug costs** from MIPS payment adjustments and eligibility calculations;
- **Eliminates improvement scoring** for the cost performance category for the second, third, fourth and fifth years of MIPS;
- Allows CMS to **reweight the cost performance category** to not less than 10 percent and not greater than 30 percent for the second, third, fourth, and fifth years of MIPS;
- Allows CMS **flexibility in setting the performance threshold** for years two through five to ensure a gradual and incremental transition to the performance threshold set at the mean or median for the sixth year;
- And allows the Physician Focused Payment Model Technical Advisory Committee (PTAC) to provide initial feedback on models regarding the extent to which they meet criteria and an explanation of the basis for the feedback.

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Year 3 MIPS Proposals

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Year 3 MIPS Proposals

- **2019 Performance Threshold**
  - Proposed performance threshold set at **30 points**
- **MIPS Eligible Clinicians**
  - Expanded to include physical therapists, occupational therapists, clinical social workers, and clinical psychologists
- **Low-Volume Threshold**
  - Added a third element to the low-volume threshold determination, while maintaining the other two elements
    - Dollar Amount ($90,000) (*current*)
    - Number of Beneficiaries (200) (*current*)
    - Number of Covered Professional Services (200) **(NEW)**
- **MIPS Opt-in Policy**
  - Clinicians or groups would be able to **opt-in to MIPS** if they meet or exceed one or two, but not all, of the low-volume threshold criteria

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Year 3 MIPS Proposals

- **Quality (45%)**
  - Meaningful Measures initiative: removal of low-value, low-priority process measures to streamline clinician reporting
  - Allowing the use of a combination of collection types for the Quality performance category
  - Small practice bonus retained, moved under Quality performance category
  - Retaining the 3 point floor for **small practices** that report measures that don't meet the data completeness requirements
  - Claims-based reporting for individuals and small practices only
- **Promoting Interoperability (*formerly Advancing Care Information*) (25%)**
  - Aligning requirements with the proposed new Promoting Interoperability Program for hospitals
  - Requiring use of 2015 Edition CEHRT
  - Reducing the number of objectives and measures; adding opioid-related "bonus" measures
  - Simplified scoring based on performance (report measures from four objectives for a total of 100 points)
- **Improvement Activities (15%)**
  - Added six new IA's and revised one IA
- **Cost (15%)**
  - Addition of 8 episode-based cost measures, largely impacting procedure-based specialties (e.g., cataract surgery, knee arthroplasty)

Proposed 2019 Allergy/Immunology Specialty Measure Set

Measure #	Measure Title	Claims	Registry/ QCDR	CEHRT
110	Preventive Care and Screening: Influenza Immunization	✓	✓	✓
111	Pneumococcal Vaccination Status for Older Adults	✓	✓	✓
130	Documentation of Current Medications in the Medical Record	✓	✓	✓
160	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis			✓
226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	✓	✓	✓
238	Use of High-Risk Medications in the Elderly		✓	
317	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	✓	✓	✓
338	HIV Viral Load Suppression (OUTCOME)		✓	
340	HIV Medical Visit Frequency		✓	
374	Closing the Referral Loop: Receipt of Specialist Report (HIGH PRIORITY)		✓	✓
402	Tobacco Use and Help with quitting Among Adolescents		✓	

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Additional A/I-Focused Measures Available for Reporting

Measure #	Measure Title	Claims	Registry/ QCDR	CEHRT
331	Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse) (HIGH PRIORITY)		✓	
332	Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) (HIGH PRIORITY)		✓	
333	Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse) (HIGH PRIORITY)		✓	
334	Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse) (HIGH PRIORITY)		✓	
374	Closing the Referral Loop: Receipt of Specialist Report (HIGH PRIORITY)			✓
398	Optimal Asthma Control (HIGH PRIORITY)		✓	
444	Medication Management for People with Asthma (HIGH PRIORITY)		✓	

MIPS Performance & Feedback

- 2017 MIPS performance scores & feedback
  - Available on QPP website using EIDM credentials
  - Provides final score and payment adjustment information
- 2019 MIPS payment adjustment ”targeted review”
  - Request through September 30, 2018 using your EIDM credentials
  - ***Targeted review decisions are final***

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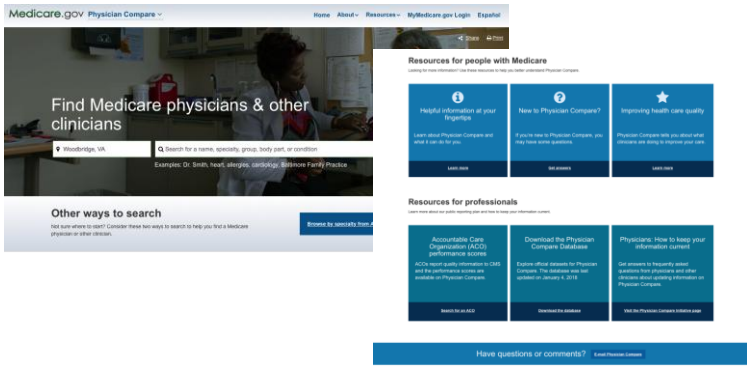
Physician Compare: Your Data is Public!



Educate your staff on the measures

1. Educate your providers and staff on each of the measures that are relevant to your practice.
2. Understand how YOUR EHR documents the measures. Know what to document in the chart. Example: For history of tobacco use: Do you use **user created** terms or system created terms? Which one will actual count the measure or will they both?
3. Run reports by provider weekly and monthly.
   - Make sure the measures are being calculated. If there is a problem with your calculations (Num/Dem), identify where the problem is, workflow, staff or EHR system, and correct it.
   - Contact your EHR vendor ASAP to report a potential system problem.

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Example:
MU Pocket Card for clinical staff.

Meaningful Use-All Staff documenting in the patient chart.

- **Continue current** documentation guidelines. Especially remember the following:
- **Medication Reconciliation**-Reconcile **All** medications on **ALL patients** and if they are on NO medication, drop down No Current Meds and reconcile.
- **Tobacco Use (Smoker or Non-smoker) –**In History, choose from short list and drop a new tobacco use on everyone. If a smoker or formal smoker, must list tobacco type and usage in the second section on history. **In A&P**, if smoker, use the protocol Nicotine dependence-F17.200 which includes Smoking Cessation (99406) and educational material. **MUST drop Protocol every 24 months.**
- **Flu and Pneumonia vaccine**-**If received in office**: document under Immunizations if patient had in our office or **if received at PCP/other facility**-Under History-Health Maintenance (add date and comment whether they received the vaccine or not).
- **Hypertension, Essential /High Blood Pressure**-if patient has this condition, put in the **History-Other Past History** section and if their BP is over 140/90 have patient rest/wait and retake. Put the best BP in the vitals. Hopefully, it is lower than 140/90
- **In A&P-ALL PATIENTS**-in addition to the diagnoses that patient is being seen for, add the following: **Protocol-** Nutrition and Exercise education **Returns**-How to access health information online and User added education
- **Patient Messages**-Send a message to patients that have been seen the day before that have a Web Account. If no other message needs to be sent, copy .**web** from system manager. Make sure your name is on the message, and use that message..

Reporting Example of PI transition

- **Know your scores**

Measure		Num	Den	Group Score(%)
Electronic Prescribing		12444	14674	85
Health Information Exchange		624	639	98
Patient Specific Education		3894	4093	95
Medication Reconciliation		1375	1491	92
Patient Electronic Access-Timely Access		3080	4093	75
Patient Electronic Access-VDT		318	4093	8
Secure Messaging		493	4093	12

- Research your outliers. Find out why Electronic Prescribing is only 85%??
- Research and find solutions to increase your scores.

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Example of Quality Report

ID	Measure	Name	Num	Dem	IPP	Exc	Exc	Perf Rate	Score
0111	CMS 127	Pneumonia Vaccination Status for Older Adults	326	466	466	0	0	70	8.5
0369	CMS 158	Pregnant women that had HBsAg testing	0	0	0	0	0	0	3
0128	NQF 0421	Preventive Care and Screening Body Mass Index Screening and Follow Up Plan	1921	2038	2048	10	0	94.3	10
0134	NQF 0418	Preventive Care and Screening for Clinical Depression and Follow Up Plan	0	2192	2353	161	0	0	3
0317	CMS 22	Preventive Care and Screening for High Blood Pressure and Follow Up Documented	529	1686	1837	151	0	31.4	7.4
0110	NQF 0041	Preventive Care and Screening Influenza Immunization	1876	2515	4020	0	154	75	9.7
0226	NQF 0028	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention						79	3.6
0226	NQF 0028 | 1	Preventive Care and Screening Tobacco Use Screening	520	524	524	0	0	99.2	0
0226	NQF 0028 | 2	Preventive Care and Screening Tobacco Use and Cessation Intervention	16	39	524	0	0	41.0	0
0226	NQF 0028 | 3	Preventive Care and Screening Tobacco and Cessation Intervention if Tobacco user	499	524	524	0	0	95.2	0

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2017 Final Score

The Final Score At A Glance

The Final Score is achieved by adding the points you earned in each Performance Category

Performance Category Scores

Quality	56.28 of 60
Advancing Care Information	25 of 25
Improvement Activities	15 of 15

How is the Final Score calculated?

Payment Adjustment
+1.81%

Payment Adjustment Date
January 1, 2019

What does this mean?

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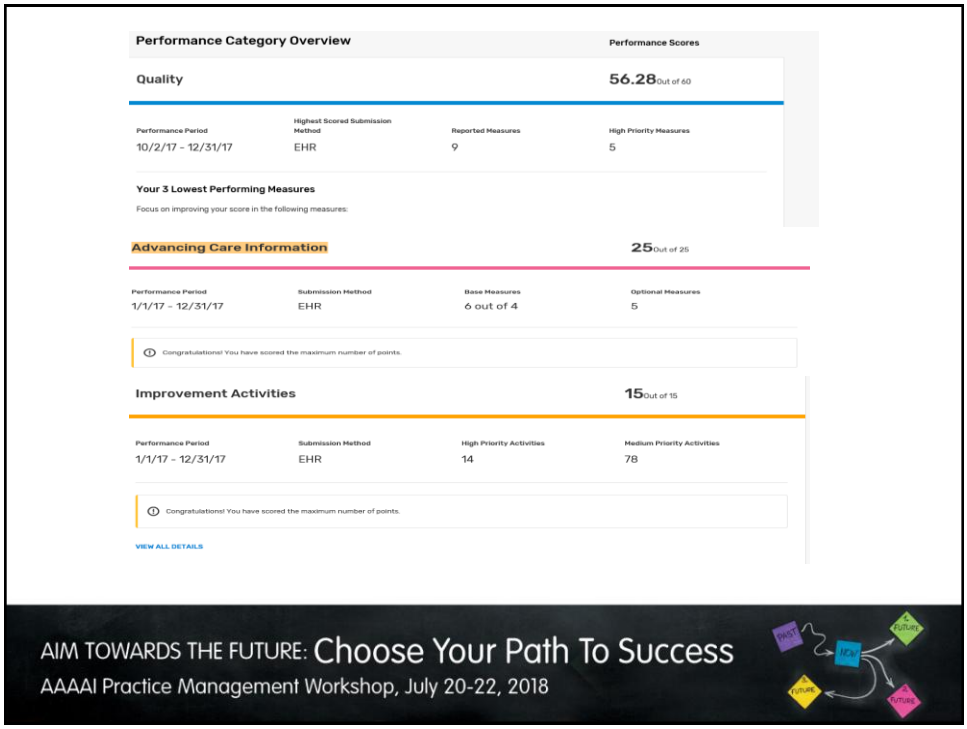

Work plan for 2018

Improve documentation on:

- Pneumococcal vaccine history (65.84%)
- Tobacco Use: 3 part process-identify smoker, type of, counsel/educate (96.95%)
- Weight assessment, counseling, nutrition (62.81%)
- Closing the referral loop (51.32%)
- Screening High Blood Pressure (29.85%)
- Adding additional patient diagnoses to patient history

More staff involvement:

- Send follow up patient messages-this will hopefully improve our secure messages
- Set work plans for employees/providers that need additional training
- Create activities to improve documentation

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Review and Ask questions

- Review the workflow processes you have set in place for your practice.
- Review the ever-changing guidelines and resources often.
  - **EHR vendor-client forums, best practices**
  - **QPP website https://qpp.cms.gov/**
  - **Outside consulting firm**

Ask for help…it's overwhelming!

MedPAC

MedPAC Recommendation on MIPS Program

- MedPAC Recommendation:
  - *The Congress should eliminate the current Merit-based Incentive Payment System (MIPS); and*
  - *Establish a new voluntary value program in fee-for-service Medicare in which:*
    - *Clinicians can elect to be measured as part of a voluntary group, and*
    - *Clinicians in voluntary groups can qualify for a value payment based on their group's performance on a set of population-based measures.*
- Passed in a 14-2 vote, with Commissioners Alice Coombs, MD and David Nerenz, PhD opposing.
- Most commissioners agree MIPS is unsustainable; many commissioners uncomfortable with "voluntary value program" replacement

MedPAC Recommendation/Policy Options for Medicare Physician Payment

- MedPAC Recommendation:
  - *For calendar year 2018, the Congress should increase the calendar year 2018 payment rates for physician and other health professional services by the amount specified in current law.*
- Commission passed unanimously
- MedPAC Policy Consideration:
  - *Increase payment rates for ambulatory E/M and psychiatric services by 10% for all physicians, offset by a 3.8% reduction for all other services*
- Commission generally supportive of E/M increases for cognitive specialties.
- Policy consideration included in June 2018 *Report to the Congress*.

2019 MPFS Proposals

2019 MPFS Proposals

- **Evaluation and Management (E&M) Services**
  - Significant proposed changes in documentation/coding
  - Single, blended payment rates for new/established patients for office/outpatient E/M (Levels 2-5)
  - New add-on codes for primary care/non-procedural specialties (e.g., A/I specialty)
  - Multiple procedure payment adjustment when E/M visits are furnished in conjunction with other procedures
- **Virtual Care**
  - Separate payment for "virtual check-in" by phone or other telecom device
  - Separate payment for remote evaluation of recorded video/images submitted by patients
  - Separate payment for interprofessional internet consultation

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2019 MPFS Proposals

- **WAC-Based Payment for Part B Drugs**
  - Reducing the 6 percent add-on for WAC-based payments for new Part B drugs when ASP is unavailable to 3 percent
- **Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging**
  - Revising the significant hardship criteria in the AUC program to include:
    - 1) insufficient internet access;
    - 2) electronic health record (EHR) or clinical decision support mechanism (CDSM) vendor issues; or
    - 3) extreme and uncontrollable circumstances
  - Allow AUC consultations, when not personally performed by the ordering professional, to be performed by auxiliary personnel
- **Practice Expense**
  - Major reductions in direct PE's (i.e., supply pricing) for **CPT codes 95165 and 95004**
- **Conversion Factor**
  - The proposed 2019 PFS conversion factor is **$36.05**, a slight increase above the 2018 PFS conversion factor of $35.99
- **Overall Impact to A/I Specialty: -5%**

Fee Schedules and Allowables

Make your Practice Management System work for YOU!

- **EACH YEAR**, review participating insurance carrier fee schedules/ allowables. Make the necessary changes in your system. You need to know what you are **supposed** to be getting paid.
- Medicare and Medicaid are the easiest…they are on their websites for easy download.
- Load the new fee schedules each year. Most systems will have an effective date; so load them as soon as possible.
- Most PM systems allow you or will help you download a fee schedule directly into your system.
- Periodically, run payment analysis reports or carrier reimbursement reports reviewing insurance companies that are not paying correctly.

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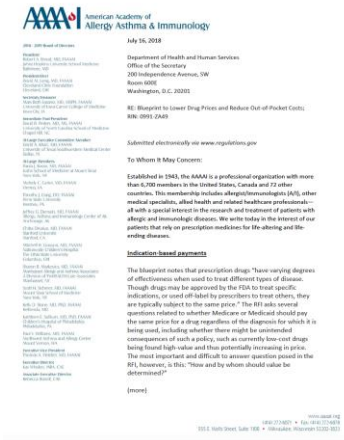
Other Key Federal Issues

Drug Pricing Blueprint

- Indication-based payments
- Moving drugs from Part B to Part D
- Part B Competitive Acquisition Program (CAP)
- Co-pay discount cards
- Pharmacy Benefit Managers (PBMs)
- Protected classes
- Sole-source drugs



American Academy of Allergy Asthma & Immunology

July 16, 2018

Department of Health and Human Services
Office of the Secretary
200 Independence Avenue, SW
Room 600E
Washington, D.C. 20201

RE: Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs; RIN: 0991-2A49

Submitted electronically via www.regulations.gov

To Whom It May Concern:

Established in 1943, the AAAAI is a professional organization with more than 6,700 members in the United States, Canada and 72 other countries. This membership includes allergists/immunologists (A/I), other medical specialties, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases. We write today in the interest of our patients that rely on prescription medicines for life-altering and life-ending diseases.

Indication-based payments

The blueprint notes that prescription drugs "have varying degrees of effectiveness when used to treat different types of disease. Though drugs may be approved by the FDA to treat specific indications, or used off-label by prescribers to treat others, they are typically subject to the same price." The RFI asks several questions related to whether Medicare or Medicaid should pay the same price for a drug regardless of the diagnosis for which it is being used, including whether there might be unintended consequences of such a policy, such as currently low-cost drugs being found high-value and thus potentially increasing in price. The most important and difficult to answer question posed in the RFI, however, is this: "How and by whom should value be determined?"

(more)

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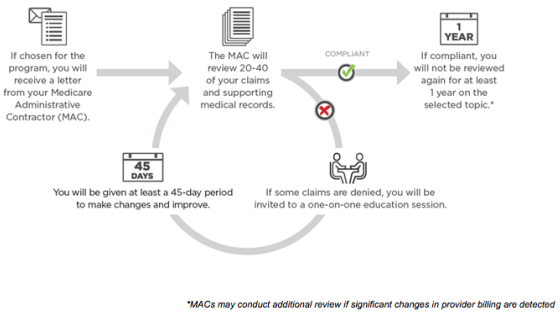
Medicare Advantage & Part D

- Medicare Advantage (MA) and Part D
  - Quality measures used in "Star Ratings"
    - AAAAI supported a new "stars measures" to address various challenges in MA and Part D, including a survey of physicians experiences. CMS said it is considering these and other measures for future years of the MA/PD Quality Ratings System.
  - "Preclusion List"
    - CMS finalized the elimination of its enrollment requirement, replacing it with a preclusion list whereby Part D drugs and MA items and services will not be covered when prescribed, ordered or performed by clinicians on the preclusion list. CMS disagreed that its criteria were overly subjective.
  - RFI on manufacturer rebate pass-through
    - CMS received over 1,400 comments, including comments from AAAAI. CMS is considering its options for a proposal to exercise its statutory authority to institute such a requirement.

"Patients Over Paperwork"

- Targeted Probe and Educate (TPE)
  - Launched in October 2017
  - Nationwide program to better target medical review, limit the number of medical records requested, and put an emphasis on education and assistance in correcting claims errors



"Patients Over Paperwork"

- Simplifying and Clarifying Documentation Requirements
  - CMS is working to reduce paperwork with simplified, streamlined Medicare documentation requirements for claims payment.
  - Where requirements are complicated, repetitive or unnecessary, submit suggestions to ReducingProviderBurden@cms.hhs.gov to help CMS simplify requirements.
  - CMS has already addressed a number of topics, including:
    - Allowing teaching physician to verify student's E/M visit notes
    - Explained that the signature of a scribe is never needed for payment
    - See more on CMS' website

"Patients Over Paperwork"

- Posting Proposed Recovery Audit Review Contractor (RAC) Review Topics
  - CMS began posting a list of review topics that have been proposed, but not yet approved, for RACs to review.
  - Topics will be listed, on a monthly basis, on CMS' Provider Resources page along with details about the proposed reviews, such as:
    - Name of the Review Topic
    - Description of what is being reviewed
    - State(s)/MAC regions where reviews will occur
    - Review type (complex review/automated review)
    - Provider type
    - Affected code(s)
    - Applicable policy references

Drug Compounding

- **Drug Quality and Security Act**
  - Enacted in November 2013
  - Prompted by nationwide fungal meningitis outbreak that killed 64 patients due to contaminated compounded medications prepared by the New England Compounding Center (NECC)
  - Policymakers granted the US Food and Drug Administration (FDA) more authority to regulate and monitor the manufacturing of compounded drugs
- ***FDA Draft Guidance - Insanitary Conditions at Compounding Facilities***
  - Issued in August 2016
  - Proposed burdensome requirements for physician compounders, to include maintaining primary engineering controls such as those used by outsourcing facilities that manufacturer drug compounds for sale
  - FDA recently signaled in its **2018 Compounding Policy Priorities Plan** that it intends to reissue the draft guidance to address physician compounding concerns

Drug Compounding

- **US Pharmacopeia (USP) General Chapter <797> – *Sterile Compounding***
  - Major revisions proposed in September 2015, including the elimination of the exception for allergen extracts as compounded sterile products (CSPs) from certain requirements
  - Proposed revisions significantly increase burden on physician compounders
  - In response to the more than 8,000 comments received due to the proposed revisions, USP appointed "expert consultants" to participate (as non-voting representatives) on the USP Compounding Expert Committee that is responsible for updating the <797>.
    - **Andrew Murphy, MD**, a private practicing allergist serves in this capacity
  - A second draft will be available for pre-review in July 2018, with comments due late in November 2018. The final version expected in December 2019.
  - FDA and state regulators rely on or defer to USP General Chapters
  - AMA key partner in coalescing physician specialties and representing physician concerns on compounding
- **Federation of State Medical Boards (FSMB)**
  - In early 2016 and late 2017, FSMB issued two separate position statements on "Compounding of Medications by Physicians"; both were met with criticism
  - FSMB decided to postpone finalizing the policy until FDA and USP have completed work on their guidance and standards
  - FSMB stated it does not intend to routinely inspect physician offices that compound, noting that the Board of Pharmacy has assumed this role (in spite of concerns by physicians)

What's on deck?

Coming soon!

- **Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction:** *This proposed rule would reform Medicare regulations that are unnecessary, obsolete, or excessively burdensome on healthcare providers and suppliers. This rule would increase the ability of healthcare professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert resources away from furnishing high quality patient care.*
- **Medicare Shared Savings Program; Accountable Care Organizations:** *This proposed rule would make changes to the regulations for the Medicare Shared Savings Program for Accountable Care Organizations (ACOs), including facilitating transition to performance-based risk and other program flexibilities, additional waivers for patients and doctors, and policies for ensuring program integrity and sustainability.*
- **Removal Of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection:** *No details*

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Questions?