American Academy of Allergy Asthma & Immunology

AAAAI Regulatory Priorities & Strategic Plan

Promoting Excellence in Allergy, Asthma and Immunology Care through Regulatory Advocacy

Regulatory Priority	Issue Overview	Potential Impact on A/I Practice	Timeline	Potential Tactics	Recent AAAAI Activity	Likelihood for Desired Outcome/Value of Engagement
Ensuring Adequate Coverage and Reimbursement for Allergy, Asthma and Immunology Care						
Misvalued Code (MVC) Initiative	CMS continues to revise its policies aimed at identifying and addressing potentially misvalued services, including developing "code screens" and ratching down values for "overvalued" services as part of the ongoing initiative.	AAAAI maintains an interest in the MVC initiative to the extent allergy, asthma and immunology services are identified for review, as reviews typically call for reductions in RVUs, thus lower reimbursements for key services.	Ongoing through annual Medicare physician fee schedule rulemaking activities (summer and fall) **Summer 2015:** CMS 2016 MPFS proposed rule includes A/I codes on MVC list (CPT 94010, 95004, and 95165). **Fall 2015:** CMS 2016 MPFS final rule released. CMS agreed to remove CPT 94010 from the misvalued code list, but CPT 95004 and 95165 remain. **Summer/Fall 2016**: In the 2017 MPFS, CMS proposed and subsequently finalized maintaining the RVUs for CPT 95165. **Summer 2017**: CMS proposed reductions in practice expense (PE) for 95004 based on AMA RUC recommendations.	• Respond to proposed regulations • Participate in the AMA RUC • Meet with CMS • Evaluate current codes that may be targeted in future potentially misvalued services initiative	AAAAI, in collaboration with other A/I provider organizations, engaged in the AMA RUC process to preserve the values for CPT 95004 and 95165. In the 2017 MPFS final rule, CMS agreed to maintain the RVU for CPT 95165. At that time, CMS indicated an interest in additional costs data for 95004, and the AAAAI, ACAAI and AAOA worked together with its consultant to provide that data. In the 2018 MPFS proposed rule, CMS proposes to accept AMA RUC recommenations that would reduce PE for this code.	Historically, CMS had adopted approximately 93% of the AMA RUC recommended values. Scrutiny of the AMA RUC by policymakers and policy advisors, including Congress and MedPAC, CMS began adopting fewer AMA RUC recommendations. In the 2018 MPFS, CMS adopted the vast majority of AMA RUC recommendations. CMS is likely to adopt the reductions in PE for 95004, as proposed.
E/M Services	Ongoing concerns about the definition and value of E/M services has prompted a group of stakeholders, known as the Cognitive Care Alliance (CCA), to recommend an extensive research effort to revise and revalue E/M services, especially work inputs.	A/I physicians use E/M codes and may benefit from the availability of more precise and accurate services and values.	**Summer 2015:** Proposals related to this effort included in CMS' 2016 MPFS proposed rule **Fall 2015:** CMS 2016 MPFS final rule released **Fall 2016:** In its 2017 MPFS, CMS finalized	• Respond to comment solictations and proposed regulations • Meet with CMS • Meet with Hill Staff • Participate in CCA and engage other medical societies	AAAAI has been invited to participate in the CCA, which has been working with policymakers and regulators to encourage funding for a robust study of E/M. AAAAI provided comments on this issue in its 2017 MPFS proposed rule comments. AAAAI continues to consider engagement at a formal level.	Support is growing for this initiative among a wide array of stakeholders, including cognitive specialists, primary care providers and proceduralists. Hill staff have been very receptive. In fact, the Senate Appropriations Committee reported out the Fiscal Year 2017

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	Current E/M codes are available for all physicians billing under Medicare, but are not reflective of the various practices styles (e.g., cognitive, primary care, surgical/procedural). New definitions and values may improve the foundation of many bundled and episode based payment constructs.		several new E/M services to advance primary care and care management services. As part of that discussion, CMS also recognized public support for "another major research initiative to distinguish and revalue different kinds of E/M work". **Summer 2017**: CMS initiated a comment solicitation related to E/M documentation guidelines, but notes that it has received feedback that the E/M code set itself is outdated and needs to be revised and that some stakeholders recommend an extensive research effort to revise and revalue E/M services, especially work inputs.		AAAAI is providing comment on the 2018 MPFS proposed rule related to the E/M guidelines, urging the agency to fully eliminate the E/M documentation guidelines rather than expend years of effort modifying the current guidelines, which will never fully satisfy all stakeholders.	Labor/HHS/Education bill, which includes E&M Research. CMS actively sought comments and finalized improved payment for primary care and care management in the 2016 and 2017 MPFS proposed rules. CMS also recognized public support for "another major research initiative to distinguish and revalue different kinds of E/M work". In the 2018 MPFS propsed rule, CMS again raised the issue of the research study in the context of the effort to revise the E/M guidelines. CMS will certainly take on an effort to revise the guidelines as part of its regulatory relief efforts, but it is unclear whether an update to the E/M values will take place in the near term.
Chronic Care Management (CCM) Services/Primary Care and Care Management Services	Physicians can collect a separate fee from Medicare for managing patients with two or more chronic conditions in addition to face-to-face visits. CMS continues to identify ways to improve payment for primary care and care management.	To the extent allergy, asthma and immunology care is one or more of the beneficiary's diagnoses; AAAAI may have some interest in the development of practice standards/ requirements and relative value units (RVUs) associated with the implementation of these new codes. Also, given A/I physicians provide primary care and care management services for their patients, any new	Ongoing through annual Medicare physician fee schedule rulemaking activities **Summer 2015:** Proposals related to this effort included in CMS' 2016 MPFS proposed rule **Summer 2016**: CMS released its 2017 MPFS proposed rule, which included proposals related to E/M services and primary care and care management services,	• Monitor and engage in the development of practice requirements/standards for the CCM codes • Monitor and engage in development of RVUs for CCM codes • Encourage the development of other chronic care management codes that are more applicable and/or specific to A/I	CMS notes that uptake of these services has been limited. In its 2016 MPFS comments, AAAAI urged the development of additional codes for managing one chronic condition. CMS noted it was considering the input from the provider community and would make some changes in 2017. In April 2016, AAAAI wrote a letter to CMS (consistent with the ACP) seeking support for ACP developed CPT codes and modifiers that would help cognates with improved payment for primary care and care management services. In its 2017	AAAAI will want to monitor use of the new CCM codes by A/I. CMS finalized significant modifications to the CCM codes, which will allow A/I specialists to more readily use and bill for these services. More work is needed, and CMS is poised to make some of the requested changes in light of its regulatory relief initiatives.

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		and/or revised policies associated with primary care and care management will be important.	including modifications to the CCM criteria **Fall 2016:** CMS' 2017 MPFS final rule emphasized primary care and care management services, as well as modified the criteria for billing CCM services, making it much easier for A/I physicians to utilize these codes **Summer 2017**: CMS seeks input from providers on ways to reduce administrative burden in providing CCM services		MPFS comments, AAAAI also urge CMS to finalize new primary care, care management and care coordination codes, as well as improve access to existing CCM codes by making the requirements less burdensome on A/I providers. CMS did finalize several new codes for primary care and care management services, and improved the billing criteria for CCM services. In 2017, AAAAI encouraged CMS to continue reducing administrative burden for CCM, and consider addressing beneficiary consent requirements. It also urged CMS to expand is outreach on CCM services to include specialists, such as A/I professionals. Educational tools should also be designed to assist specialists with the delivery of CCM services.	
Part B Drug Payment Model	Generally, CMS addressed payment for Part B drugs through its annual payment regulations, including the Medicare Physician Fee Schedule. Other regulations may also impact payment for Part B drugs. The cost and use of Part B drugs continues to be an area of focus for the agency and its contractors, as well as the Medicare Payment Advisory Commission (MedPAC).	Access to physician-administered drugs is important to AAAAI members, particularly those who are treated with Ig or Xolair for their A/I condition.	Ongoing through annual Medicare physician fee schedule rulemaking activities **Spring 2016:** CMS released Part B Drug Payment Model for comment **Fall 2016:** Anticipated release of final rule; CMS notifies Capitol Hill that the Part B Drug Payment Model will not be finalized by Obama Administration **Summer 2017**: CMS formally withdraws Part B Drug Payment Model	• Monitor and comment on Part B payment policies to ensure that access to important physician-administered drugs used in the care of patients with allergy, asthma and immunology diseases are not limited due to inadequate reimbursement and/or unfeasible local contractor policies	AAAAI submitted comments in opposition of CMS' draft Part B drug payment model, mostly in support of its lay organization – IDF – given the concerns with the process CMS used to develop the model, as well as significant policy issues, including a potential lack of access to care. There is also considerable push from other like-minded stakeholders at the federal legislative level, and Congress has weighed in urging either withdrawal or major modifications to the draft regulation. AAAAI supported an AMA resolution that would call on withdrawal, or improvement, of the model. The HOD approved the resolution and it is now AMA policy.	Given the strong outpouring of opposition, CMS notified Capitol Hill that the Part B Drug Payment Model would not be finalized by the Obama Administration. The Trump Administration recently withdrew the model officially.
High Drug Prices	The rising cost of medications is a growing concern for patients, providers and policymakers. Efforts are underway to	Epinephrine auto-injectors (i.e., EpiPen) have spiked in price over the past few months, which has prompted more concern	Ongoing through Congressional and HHS activity	• Meet with HHS • Meet with FTC • Collaborate with like-minded stakeholders, including patients and provider groups	AAAAI has prepared a policy options document to outline potential opportunities to engage on high drug prices and specifically address	Given the Congressional and regulatory attention the broader issue is receiving, the likelihood for positive change is higher.

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	identify the cause for rising drug prices and how best to address concerns about access to medications.	about the high drug price debate among the A/I community.		• Dialogue with EpiPen manufacturers • Prepare comments on the 2018 Notice of Benefit and Payment Parameters proposed rule, if applicable • Consider approaching USPSTF regarding a recommendation that epinephrine auto-injectors are considered a preventative service	concerns about access to EpiPens and AIT.	
Improving the Quality and Efficiency of Allergy, Asthma and Immunology Care						
MACRA Implementation	The Medicare Access and CHIP Reauthorization Act (MACRA) was enacted on April 16, 2015. The law established the Merit-based Incentive Payment System (MIPS) that consolidates existing Medicare quality programs (PQRS, VM and EHR/MU), as well as a pathway for physicians to participate in an Alternative Payment Model (APM). The framework for these programs is known as the Quality Payment Program (QPP).	Improving the quality and cost of allergy, asthma and immunology care is a top priority for AAAAI. Given the new MIPS will simply consolidate old programs into one, there are concerns that existing problems will remain in future years. For example, the current VM and uses PQRS as the quality benchmark and other resource use metrics to evaluate cost, many of which may be irrelevant to evaluating allergy, asthma and immunology care.	Ongoing through Medicare physician fee schedule rulemaking activities **Fall/Winter 2015:** CMS released multiple requests for comment, separately and as part of the 2016 MPFS, to inform the development of MACRA proposals **Spring 2016:** MACRA programs proposed rule released **Fall 2016**: MACRA programs finalized **Summer 2017**: 2018 QPP requrements proposed	• Collaborate with like-minded stakeholders, including patients and provider groups, on key issues and potential responses • Closely monitor activities of CMS, CMMI and the Physician Focused Technical Advisory Committee (PTAC) as MACRA implementation begins • Meet with CMS, CMMI • Submit meaningful comment on MACRA-related regulations and other comment and feedback opportunities	AAAAI has continuously engaged in the process as CMS implements the QPP. AAAAI maintains a qualified clinical data registry (QCDR) to assist with member participation in the program, and conducts outreach and education on program requirements at its Annual Meeting and Practice Management workshops, as well as through online and other media. AAAAI recently submitted comments on the 2018 QPP proposed rule.	Engagement is critical to ensure A/I physicians can meaningfully participate in MACRA programs and avoid financial penalties. So far, some AAAAI concerns have be addressed. For example, CMS agreed to maintain some of AAAAI's measures in the AAAAI QCDR. A few significant wins were realized in the 2018 QPP proposals, which we anticipate CMS will finalize this fall (e.g., use of 2014 CEHRT in 2018 and exemptions from the ACI performance category for small practices). Additional challenges still remain, for example, CMS revised the A/I specialty measure set, removing key measures and adding measures that are not appropriate for most A/I professionals. Overall, we anticipate many positive changes in the QPP for 2018.

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Quality Measurement	Section 3014 of ACA requires the establishment of a federal "pre-rulemaking process" for the selection of quality and efficiency measures for specific qualifying programs within HHS. CMS fulfills this requirement by publicly presenting measures it is considering for future adoption in December of each year. This list is then reviewed by the NQF-convened Measure Applications Partnership (MAP), which, with input from the public, makes final recommendations to CMS in February.	Improving the quality of allergy, asthma and immunology care is a top priority for AAAAI. Actively monitoring and participating in the pre-rulemaking process is a critical component for ensuring the availability of measures that are accurate and meaningful to both physicians and patients.	Ongoing through NQF-convened MAP activities and CMS' annual Medicare physician fee schedule rulemaking activities **Spring 2016:** MACRA programs proposed rule released **Fall 2016**: MACRA programs final rule released **Spring 2017:** 2018 QPP proposed rule released.	• Participate in the MAP to ensure measures adopted into federal programs are meaningful and relevant to allergy, asthma and immunology care and patients • Engage in a dialogue with CMS on the inclusion of A/I measures in its quality payment program • Submit meaningful comment on MACRA-related regulations and other comment and feedback opportunities	Despite AAAAI's request, CMS did not make any of the requested changes to its Quality Measure Development Plan (MDP), which was released May 2016. AAAAI had urged CMS to consider multiple options for addressing antibiotic stewardship through the adoption of measures and tactics that would include penicillin allergy testing. However, CMS agreed with AAAAI's sentiments in its MIPS/APMs proposed rule and implementation of an antibiotic stewardship program that measures the appropriate use of antibiotics for several different conditions according to clinical guidelines for diagnostics and therapeutics was included as a CPIA under MIPS. CMS has included a specialty measure set for A/I physicians in the MIPS quality performance category, and modifications were made to address some of our concerns. Also, CMS and AAAAI had a conference call to discuss upper-age limits on certain measures. We were able to get changes made to CMS' determination about measures in the QCDR for 2017, but not in the core measures set for MIPS. See "MACRA Implementation" See "Antibiotic Stewardship"	CMS has responded to several of our concerns. For example, in the MACRA final rule, the agency removed the Rheumatology quality measures from the A/I measure set. In Fall 2016 as part of a conference call with CMS staff, the agency agreed to maintain some of AAAAI's measures in the AAAAI QCDR. Additional challenges still remain, for example, CMS revised the A/I specialty measure set, removing key measures and adding measures that are not appropriate for most A/I professionals.
Antibiotic Stewardship	Antimicrobial stewardship promotes the appropriate use of antimicrobials (including antibiotics), improves patient outcomes, reduces microbial resistance, and decreases the spread of infections	Although an estimated 10% of persons who report a history of severe allergic reactions to penicillin continue to remain allergic their entire lives, with the passage of time, most persons who have had a	Ongoing **March 2015:** Release of National Action Plan for Combating Antibiotic-Resistant Bacteria	• Collaborate with like-minded stakeholders to develop new quality measures for use in antibiotic stewardship efforts • Possible promotion of a penicillin allergy measure for use in NQF Antibiotic Stewardship Action Team	AAAAI submitted comments to CMS's LTCF proposed rule expressing strong support for the antibiotic stewardship provisions in the rule. AAAAI explained that patients who suspect they have a penicillin allergy or who have documentation in their health record regarding a penicillin	AAAAI's efforts have been successful given the inclusion of antibiotic stewardship in MACRA requirements. AAAAI's efforts should continue to have a high impact on improving

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	caused by multidrug-resistant organisms.	severe reaction to penicillin stop expressing penicillin-specific IgE (238,239). These persons can then be treated safely with penicillin. Penicillin skin testing with the major and minor determinants of penicillin can reliably identify persons at high risk for penicillin reactions (238,239). AAAAI supports this penicillin allergy testing as part of ongoing antibiotic stewardship programs meant to address longstanding concerns about antimicrobial resistance.	**June 2015**: White House Forum on Antibiotic Stewardship **March 2016**: PACCARB Meeting	• Engage in a dialogue with CMS on the inclusion of A/I measures in its quality payment program • Submit meaningful comment on MACRA-related regulations and other comment and feedback opportunities	allergy should be tested by a board certified allergist/immunologist to verify if they are truly allergic before an alternative non-penicillin antibiotic is prescribed. Thus, AAAAI urged CMS to adopt antibiotic stewardship requirements for LTCFs and requests that it consider penicillin allergy testing and penicillin desensitization as critical parts of a comprehensive antibiotic stewardship program in LTC and other settings. In addition to legislative initiatives on this issue, AAAAI has engaged in a dialogue with the Infectious Diseases Society of America (IDSA) on the development of quality measures that would support penicillin allergy testing in quality improvement programs, such as the PQRS and the new MACRA programs. The AAAAI position statement on verification of patient-reported penicillin testing was shared with the PACCARB and is now published online. The AAAAI supported antibiotic resistance concerns in the 21st Century Cures legislation.	treatment for infections, related outcomes, as well as potentially reducing healthcare costs broadly.
Examining Emerging Payment and Delivery Models						
CMS Innovation Center	Section 3021 of the ACA creates the CMS Innovation (CMMI) to test new payment and delivery system models that reduce costs while maintaining or improving quality.	Emerging health care delivery and payment models will impact allergy, asthma and immunology practices. CMMI projects may address allergy, asthma and immunology care, or care related to allergy, asthma and immunology services. With CMMI's expanding portfolio and the Secretary's broad	CMMI has issued multiple requests for information (RFI) seeking comment on various models, including one RFI that focuses specifically on specialty practitioner payment models **Early Fall 2015:** MACRA RFI released for comment	• Collaborate with like-minded stakeholders to develop new models of allergy, asthma and immunology care delivery and payment • Submit meaningful comment on MACRA-related regulations and other comment and feedback opportunities	AAAAI follows CMMI activities and initiatives to the extent they are pertinent to A/I practice and has sought data on the number of A/I specialists in CMMI models. Most recently, AAAAI joined the Healthcare Leaders for Accountable Innovation in Medicare (AIM) Coalition which is "committed to an improved [CMMI] that is a more effective incubator for new ideas and	AAAAI continues to monitor and evaluate new and existing CMMI projects to see where they intersect with A/I practice. As Medicare moves toward alternative payment models, it will be important for AAAAI to engage and discuss with the demo sites about their experiences and to see where projects can be expanded broadly, as this will

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		authority, questions have been raised about whether clearer boundaries are necessary.	**Spring 2016:** PTAC did not recommend a proposed model for COPD		an interactive, transparent partner with stakeholder organizations."	have a significant impact on A/I practices. Noteworthy, the Physician-Focused Payment Model Technical Advisory Committee (PTAC) did not recommend a proposed model for COPD, and another model related to A/I care is expected to be submitted shortly.
Expanding Comparative Effectiveness Research in Allergy, Asthma and Immunology Care						
Patient Centered Outcomes Research Institute (PCORI)	Section 6301 established PCORI to conduct research that compares the clinical effectiveness of medical treatments. PCORI has approved 279 awards totaling more than $464.4 million to fund patient-centered comparative clinical effectiveness research projects to date.	AAAAI supports comparative effectiveness research (CER) and ensuring access to the most effective therapies available.	Ongoing funding awards, committee and other engagement announced via PCORI website and list-serve	• Consider projects that would be useful to addressing CER issues for allergy, asthma and immunology patients • Meet with PCORI leaders to address allergy, asthma and immunology care CER • Nominate AAAAI members to serve on advisory panels	N/A	N/A
Drug Compounding	Drug compounding has come under recent scrutiny given recent concerns about patient safety. The Drug Quality and Security Act (DQSA) passed in November 2013, and new FDA regulations and guidance have been released to implement provisions of the new law. Recently, the United States Pharmacopeia (USP) released guidelines that would eliminate the exclusion for allergen extract preparation, which would significantly hinder patient access to allergen immunotherapy.	Ensuring AI can continue to personalize medications for patients through drug compounding, including allergen immunotherapy, is critical.	**Summer 2014:** Proposed rule and interim/final guidance's address drug compounding released **Winter 2015:** FDA issues new guidance on drug compounding **May 2015:** Comments submitted on proposed FDA regulations **September 2015**: USP issues revised guidelines for sterile compounding for comment by the public **September 2016**: USP Compounding Expert Committee Meeting **December 2016:** FDA issues final guidance on	• Collaborate with like-minded stakeholders that are also impacted by the proposed USP revisions • Comment to FDA on impact of drug compounding on AI practice • Nominate AAAAI clinicians to relevant FDA panels • Comment on draft USP compounding guidelines • Engage in a dialogue with FDA, DoD and other relevant stakeholders • Deploy legislative strategy	AAAAI submitted detailed comments to FDA on its draft guidance document entitled, "Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application". AAAAI submitted comments to a recently revised draft of USP Chapter 797, which are referenced in statute and required for adoption by FDA. AAAAI will continue to coordinate with and support MedCHI activities in MD, and research status of similar legislation in other states has been drafted. AAAAI was successful in defeating a draft position statement developed by the Federation of State Medical Boards (FSMB). AAAAI staff and physicians attended the FSMB annual meeting in April and	The goal is to maintain the opportunity to conduct mixing of allergen extract in the allergist's office without further regulation making it unfeasible to do so. Support for maintaining the exception is growing and more likely with Congressional and DoD intervention.

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			Prescription Requirement Under Section 503A		presented concerns, as did other specialties, and were able to convince the reference committee chair to recommend that the draft position statement be withdrawn. Also AAAAI submitted, with other societies, an AMA resolution on USP concerns, which was approved by the HOD and now AMA policy. The AMA DC office continues to be engaged on this issue following AAAAI efforts to garner their support. AAAAI participated in the September 20, 2016 meeting of the USP Compounding Expert Committee in Rockville, MD. The committee discussed the revision timeline of the chapter, public comments received, and next steps. AAAAI submitted a resolution at the November AMA HOD that specifically called for protection of in-office compounding as the practice of medicine and asked that physicians' offices not be included in the "compounding facilities" definition from FDA. The resolution was adopted. In November, the AAAAI sent a letter to the Trump Transition team regarding concern about a potential 11th hour regulation/guidance related to the "Insanitary Conditions in Compounding Facilities" draft guidance issued in August. We also shared the Trump Transition Team letter with Members of Congress and reminded them of the earlier letters from Members of Congress to HHS about allergen immunotherapy. AAAAI representatives are working on the USP stakeholder meeting to be held on Feb. 2.	

Hot Topics

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Examining Emerging Payment and Delivery Models						
Accountable Care Organizations (ACOs)	Section 3022 of the ACA requires the Secretary to develop and implement a Medicare shared savings program that allows providers to voluntarily organize as ACOs and meet quality thresholds to share in any cost savings they achieve for the Medicare program.	To date, there are 424 Medicare ACOs. The program continues to grow.	Ongoing through dedicated ACO rulemaking and annual Medicare physician fee schedule rulemaking activities **Fall 2014:** CMS issued a proposed rulemaking to address recently identified challenges associated with ACOs, including exclusivity and beneficiary attribution. Comments were submitted in February, and a final rule is expected in Summer 2015. **Fall 2016:** CMS finalized Medicare ACO Track 1+ Model **Summer 2017**: CMS proposes changes to MSSP ACO program via the 2018 MPFS.	• Partner with like-minded stakeholders to engage in the development allergy, asthma and immunology-focused or cognitive-specialty led ACOs • Monitor whether ACOs are improving or diminishing allergy, asthma and immunology care delivery • Assess whether allergy, asthma and immunology services are appropriately captured and reflected, and contributory to reducing costs and improving quality in this model • Submit meaningful comment on MACRA-related regulations and other comment and feedback opportunities	AAAAI responded to CMS' proposed rulemaking seeking 1) changes to exclusivity requirements that limited most specialty providers, including A/I physicians, to participation in one Medicare ACO; 2) Improvements in how ACOs distribute shared savings; and, 3) restrictions on "gate-keeper" activity that limit access to specialists, particularly when they are not in the ACO "network". AAAAI has previoulsy inquired with CMS about the specialty distribution within ACOs, including A/I, particularly with ACO models being included as Adv. APMs in CMS' MACRA programs. These concerns were recently reiterated in the 2018 MPFS proposed rule in response to changes CMS proposes to the ACO application process.	AAAAI realized success with its request to exempt A/I from exclusivity; however, CMS did not agree to take affirmative action on addressing our concerns with access to specialty medicine or fair distribution of shared savings. CMS previously stated that it would monitor access to specialty care more based on concerns raised by the specialty provider community. AAAAI continues to raise these concerns in comments.
Intravenous Immune Globulin (IVIG) Demonstration	Authorized under Title I, section 101 of the "Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012". This three-year demonstration will enroll up to 4,000 Medicare beneficiaries. Under the demonstration there will be a per-visit payment amount for items and services needed for the in-home administration of IVIG based on the national per visit low-utilization payment amount (LUPA) under the prospective payment system for home health	The Medicare Intravenous Immune Globulin (IVIG) Demonstration is being implemented to evaluate the benefits of providing payment and items for services needed for the in-home administration of intravenous immune globulin for the treatment of primary immune deficiency disease (PIDD).	**Summer/Fall 2014:** Demo announced by CMMI and applications being accepted on rolling basis **Summer 2017**: CMS implements changes in the regulatory text related to payment for IVIG infused via DME.	• Collaborate with like-minded stakeholders, and federal entities to ensure smooth implementation and valid/reliable study results	AAAAI supports the IVIG demo and its extension. The AAAAI supported related efforts in the 21st Century Cures legislation. AAAAI recently raised concerns related to payment for IVIG when infused via DME. This issue was outlined in comments via the 2018 MPFS.	Success will mostly be defined by the success of the program and how A/I practices were able to engage. Data will be available in several months. AAAAI look to CMS to use its administrative authority to address certain changes in the payment for IVIG infused via DME while it also works on a solution through legislative efforts.

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	services.					
Reducing Regulatory Burden and Improving Medicare Program Integrity Efforts and Education						
CMS' Price/Payment Transparency Initiatives	CMS aims to makie the healthcare system more accountable and affordable by releasing data that summarize the utilization and payments for procedures and services provided to Medicare fee-for-service beneficiaries by specific inpatient and outpatient hospitals, physicians and other providers and suppliers.	Ongoing concern and confusion about public reporting of payment data require clarification by CMS, particularly given the lack of context that has been provided related to the payment data that has been released to date.	CMS has released payment data for select inpatient and outpatient hospital services, as well as all physicians. Additional data is expected to be released over the coming months and years for other providers/suppliers and programs	• Collaborate with like-minded organizations to address outstanding concerns • Meet with CMS to understand various uses for transparency data by AAAAI to drive quality improvement and efficient resource use • Conduct targeted outreach and education on the impact to allergy, asthma and immunology care physicians	N/A	Transparency will continue to expand throughout federal programs. Success will be defined in how well we can move the agency toward providing appropriate context and evaluating how A/I practices are impacted by these efforts.
Program Integrity (Fraud, Waste and Abuse)	The elimination of fraud, waste and abuse, particularly in health care, a top priority for the administration. Recently, HHS and the Department of Justice together released a new report showing that for every dollar spent on health care-related fraud and abuse investigations in the last three years, the government recovered $7.90.	Ongoing concern and confusion about CMS program integrity initiatives require clarification by CMS. Legislative effort may be warranted to address the regulatory burden and lack of transparency related to these program integrity efforts.	Ongoing	• Collaborate with like-minded organizations to address multiple outstanding concerns • Conduct targeted outreach and education on the impact to allergy, asthma and immunology care physicians, including OIG identified areas of priority and other RAC/MAC/CERT and PSC activity • Consider legislative approach to addressing regulatory burden of CMS' fraud, waste and abuse programs on AAI physicians • Educate members on compliance with new and revised requirements related to program integrity	Collaboration with JCAAI to provide regular updates about HHS action on various fraud, waste and abuse programs, including the RACs. Ongoing monitoring of RACs and other audit programs. AAAAI recently participated in an AMA convened meeting of specialites where CMS staff provided updates related to its program integrity efforts, including the new initiatives: Targeted Probe and Educate (TPE), which replaces Original Medicare Review; Documentation Requirement Simplification (DRS); Electronic Medical Documentation InteroperabilityINitiative 9EMDI) Implementation Guide; Listening Sessions; and, MAC/RAC Portals. Regarding RACs, CMS noted a major program enhancement was the initiation of a 30-day waiting period before sending the claim for adjustment, which allows a practice to revise billing or appeal. CMS noted that ZPICs are being consumed by the UPIC contractors.	A survey of AI practices would be helpful to determine what the biggest pain points with regard to RAC, MAC and other audit requests, as well as other issues with coverage at the local and national levels.

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HIT Patient Safety/Adverse Events	The US Food and Drug Administration (FDA) is taking a more active role in the regulation of EHR technology as a result of FDASIA and its view that EHRs may constitute a medical device.	Little direction has been shared with providers on mechanisms for addressing patient safety issues related to the use of HIT.	Ongoing efforts between FDA, ONC and other private organizations, such as the Bipartisan Policy Center (BPC) **Spring 2015:** CMS released its proposed rule on Stage 3 meaningful use a for future years of the program, and a rule that would modify Stages 1 and 2 of the current program **Fall 2015:** CMS released final 2015 certification criteria rule, but offered no comment period.	• Engage in discussions with providers and federal agencies on how to improve patient safety/adverse events in allergy, asthma and immunology care related to EHR use	CMS did not address AAAAI's request that the agency modify its Conditions of Participation (CoP) related to a hospital's quality assessment and performance improvement (QAPI) activities to address adverse patient events, nor did it address the other related recommendations since they were largely outside the scope of the rule. NQF recently released a report related HIT patient safety.	It is important to ensure certified EHR products capture patient safety events and that that information is disseminated to providers and used to improve EHR systems. AAAAI will continue to use engagement opportunities to express concerns about this issue and offer suggestions for improvement.
Improving Access to Allergy, Asthma and Immunology Treatment and Therapies						
United States Preventive Services Task Force (USPSTF)	The ACA authorized CMS to modify the coverage of any Medicare-covered preventive service in place at the time of its enactment to make the coverage consistent with USPSTF recommendations. The ACA provision specifically allowed CMS to withhold Medicare payment for these currently-covered preventive services that have an USPSTF grade of D (not recommended). The authority Congress granted CMS through a 2008 law to expand coverage to additional preventive services already comes with the stipulation that they be evidence-based.	Coverage for various allergy, asthma and immunology services is a top priority for AAAAI.	Ongoing activity of the USPSTF. Nominations are due May 17.	• Monitor USPSTF recommendations and make comment where necessary to ensure access to important allergy, asthma and immunology services	N/A	N/A
Engaging Allergy, Asthma and Immunology Providers in the Federal Regulatory Process						
Federal Advisory Committees	The federal government seeks the input of experts	AAAAI members can provide valuable insight to federal regulatory	Ongoing	• Nominate AAAAI members to serve on multiple federal	N/A	AAAAI nominated Dr. Routes to an HRSA Advisory Committee. AAAAI should

Hot Topic	Issue Overview	Potential Impact on A/I Practice	Timeline	Potential Tactics	Recent AAAAI Activity	Likelihood for Desired Outcome
	serving on multiple federal advisory committees.	agencies through membership on various federal advisory committees.		advisory committees, as warranted		also consider nominating A/I leaders to relevant USP workgroups.
Engagement in Federal Regulatory Initiatives	The federal government routinely sponsors initiatives that may impact allergy, asthma and immunology care.	AAAAI members can provide valuable insight to federal regulatory bodies through providing comment on federal regulatory activities and initiatives that may impact patient care.	Ongoing	• Seek opportunities for comment to help establish the AAAAI brand and expertise	N/A	N/A

Other Issues Considered

Medicare Advantage and Part D Programs
Implementation of FDASIA
Hospital Outpatient Quality Reporting Program
Physician-directed Applications (i.e. "Off-label Use")
Hospital Value Based Purchasing