Advocacy Council:
Update for CSAAI 2022

Warner W. Carr, MD FACAAI
Chairman - Advocacy Council of the ACAAI

American College of Allergy, Asthma & Immunology

Objectives

At the end of this discussion participants will be able to:

- Who is the Advocacy Council of the ACAAI?
- Understand what is a physician advocate and who we advocate for?
- What are the critical issues currently being faced by providers and patients and how do advocate to address them?
- How is the ACAAI Advocacy Council doing their job?
- How can you be a Physician Advocate?
- Understand the efforts of the ACAAI in response to the COVID-19 Pandemic.
- Hot topics on the horizon

ADVOCACY COUNCIL
of the American College of Allergy, Asthma & Immunology

The Advocacy Council is like air-conditioning on a hot summer day - only missed if we're not working!

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The Advocacy Council: Who Are We?

- The group formerly known as the JCAAI.
  - Transition in 2015
  - Structurally independent
- House of Delegates & Practice Management Committee now under same umbrella.
- Current Officers and Staff:
  - Warner W. Carr, MD, FACAAI – Chairman
  - Travis A. Miller, MD, FACAAI – Vice chair
  - James M. Tracy, MD, FACAAI – Immediate Past Chairman/Treasurer of ACAAI
  - James Sublett, MD, FACAAI - Executive Director of Advocacy and Governmental Affairs
  - Gary N Gross, MD, FACAAI – Coding Consultant
  - Sue Grupe - Director of Advocacy Administration

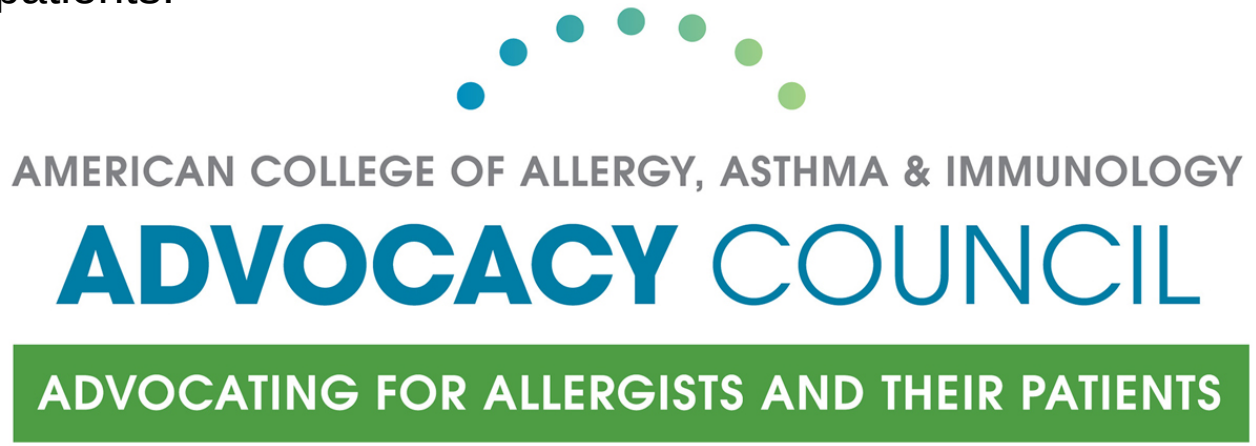
Board Members	
Mark Corbett, MD – ACAAI President	Purvi Parikh, MD
Alnoor Malick, MD	M. Razi Rafeeq, MD – HOD Speaker
Kathleen May, MD – ACAAI Pres. Elect	Melinda Rathkopf, MD
Dane McBride, MD	

The Advocacy Council: Who Are We? Behind the Scenes… Lobbying

- **What is lobbying?**
  - Defensive lobbying – Watch for important legislation both nationally and locally
    - Use and access the critical tools for surveillance
  - Offensive lobbying –
    - Understand how regulations on a state and national level are developed
    - Legislative and policy making structure and help with accessibility to address relevant concern – i.e. Advocate for our patients and us
- **The ACAAI Team**
  - Capital Associate
    - Mr. Bill Finerfrock
    - Matt Reider
    - Weekly updates – i.e. COVID-19 Federal response
  - Legal Support
    - Becky Burke

We had a make over….

- A redesigned logo and new tagline for the new year
- Part of the College's Vision Forward Strategic Plan
- Forecasts our philosophy to stakeholders, and, ultimately, elevate the profile of the Advocacy Council.
- Supports the advancement of the specialty and meets the needs of the practicing allergists/immunologists
- Stands for a fresh and expanded commitment in the College's ongoing efforts to represent you and your patients.



What is a Physician Advocate?

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- As physicians, we often find ourselves at the crossroads of a unique and sometimes intimate knowledge of patient needs.
- This places us at a point with the ability to leverage influence on health care system delivery, social barriers, and even impact political policy.
- We need to be very familiar with both patient needs and incorporating social factors of health into patient care.
- Understanding and adapting to an ever-changing healthcare landscape is critical.
- Understand healthcare model as well as front line challenges
- Ensure practice financial viability, especially in the private practice arena

Who are we advocating for?

- First and for most we advocate for our patients…
  - Access to primary care
  - Access to specialty care
  - Affordable Medications with adequate reimbursement and coverage
  - Transparent and affordable coverage
- Second for our Community
  - Understand our community and its specific needs
- Third for ourselves and our Specialty
  - Physician often carry significant debt burdens
  - Adequate reimbursement
  - Recognition of differing population mixes
    - Urban, Suburban, and rural differences
- Make a living so as continue to address our patient and community responsibilities

Critical issues currently faced by allergists and our patients

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1. Reducing Prior Authorization Burdens.
2. Maintaining Telehealth coverage/payment policies post pandemic
3. Fixing the Good Faith Estimate provisions in the No Surprises Act to reduce provider burden
4. Advocating to continue the 2% Medicare sequester
5. 95165 issues (dose limitations)

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Prior Authorization

- Patients can be denied access to their medicine for days, even weeks because of a practice called “prior authorization.” It’s the process whereby insurance companies must approve a physician-prescribed medicine, procedure or test before a patient can get coverage.

- Delays can be frustrating, painful or even dangerous for patients—especially for patients with chronic conditions.
  - Meanwhile, physicians and their staff spend hours filling out multi-page forms and submitting labs and patient records. Even then, approval is not guaranteed.
  - If the insurer denies coverage, patients and their physicians can appeal. But that delays treatment even longer and may not lead to approval.

- Insurers claim prior authorization stops unnecessary use of expensive treatments. But it’s become a cost-cutting tool that makes it hard for patients to access treatment, especially newer, more innovative medicines.

- In some cases, the frustrating process may lead patients to abandon treatment altogether.

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
  - Drug specific PA letter generator and other tools and advise

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AfPA | Alliance for Patient Access

Respiratory Therapy Access Working Group

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No Surprises Act

- December 2020 congress passed the No Surprises Act (NSA)
  - intended to protect patients from unexpected out-of-network (OON) “surprise” medical bills for care provided at an in-network hospital.
  - creates an arbitration process called Independent Dispute Resolution (IDR) to resolve payment disputes
  - Also includes an advanced explanation of benefits (AEOB), which requires providers to send their good faith estimate to the patient’s health plan.

- Requirement to provide uninsured or self-pay patients with a “good faith estimate” (GFE) for the cost of their care
  - either upon request by the patient or when the patient schedules care.
  - GFE is intended to provide price transparency for uninsured patients and to allow insured patients to compare the self-pay price to their out-of-pocket costs if the bill was submitted to their health plan.

- GFE requirement took effect January 1, 2022

No Surprises Act

- Providers are prohibited from balance billing the patient for more than their cost-sharing.
- The second component is a requirement to provide an advanced “good faith estimate” (GFE) of the anticipated cost for care to uninsured and self-pay patients either upon request or when scheduling care.
- **This provision applies essentially to all health care providers**.
- Self-pay patients have insurance but choose not to have the bill submitted to their health insurance and pay out-of-pocket instead.

Good Faith Estimates

- Many practices already provide cost estimates to patients upon request this policy establishes a timeline.
  - If an uninsured or self-pay patient requests a GFE, the provider has 3 business days to issue the GFE.
  - If an uninsured or self-pay patient schedules care at least 10 business days in advance, the provider has 3 business days to issue the GFE.
  - If an uninsured or self-pay patient schedules care at least 3 business days in advance, the provider has 1 business day to issue the GFE.
  - If an uninsured or self-pay patient schedules care less than 3 business days out, then the provider is not required to issue an uninsured or self-pay GFE.

Good Faith Estimates

- The GFE must include services that the provider “reasonably expects” to provide – the specific costs estimates – with service codes.

- The GFE should also “include the period of time during which any facility equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services that would not be scheduled separately by the individual, are furnished.

- It is the intent of this definition of ”period of care” to clarify that the good faith estimate should include all of the items or services that are typically scheduled as part of a primary item or service for which an individual does not need to engage in additional scheduling.”

- It also aims to provide patients with the ability to compare their health plan’s price with the self-pay price while providing greater price transparency for uninsured patients.

Medicare cuts

- The Advocacy Council, along with other organizations, has been successful in advocating for legislation to alter Medicare physician payment cuts scheduled to begin Jan 1.
  - The legislation required a recalculation of allergy reimbursements.

- As a result of legislation enacted by Congress in December 2021, there is a temporary one-year increase in the Medicare physician fee schedule reimbursement of 3% above what was originally proposed for 2022.
  - The previously scheduled 3.75% decrease will result only in a 0.75% decrease.

- In addition, the 2% Medicare sequestration cuts scheduled to go into effect Jan. 1 have been delayed through March 31, 2022.

- The legislation will reduce the amount of the sequester cuts for the following quarter, resulting in a 1% reduction from April 1 – June 30, 2022.

Medicare cuts

- On July 1, the full 2% sequester is set to go back into effect.

We will continue to monitor these issues and keep you informed of developments.

- **April 1, 2022**: A 1% Medicare sequester cut goes into effect.
- **July 1, 2022**: The Medicare sequester cut increases to 2%.
- **Jan. 1, 2023: Many cuts come back into effect**:
- The one-year 3% PFS boost expires, resulting in a 3% cut from 2022 rates.
- The 4% cuts to Medicare (and other programs) associated with the PAYGO impact of 2021 legislation kicks-in (plus any additional legislation enacted in 2022).

- However, without Congressional action, the allergy/immunology specialty could see a decrease in Medicare reimbursement of up to 9.5% in 2023.

Restrictions on 95165: Allergy Extracts

- 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 these policies

- Cigna nationally has raised the limit to 150 after correspondence from the AC

Restrictions on 95165: Allergy Extracts

- Our members continue to experience issues with CPT 95165.
- Most recently, UHC has requested documentation for 95165 claims; members submit the documentation and receive a request for more documentation again and again. Not only are members frustrated, but they aren't being paid, so you can understand the urgency to this request.
- College leadership have spoken Academy leadership and all have agreed to work together to help resolve this issue.
- WE HAVE FORMED A NEW TASK FORCE TO ASDDRESS THIS

Telehealth and the future of healthcare delivery

- March 3, 2022 a letter was sent from multiple organizations, to include the ACAAI and AC, to congressional leadership with recommendations for legislation expanding telehealth flexibilities beyond the declared public health emergency (PHE) for the COVID-19 pandemic.

- Studies have shown the benefits of the use of telehealth.

- A recent study by the Centers for Disease Control and Prevention (CDC) concerning the use of telehealth in health centers suggested that “telehealth can facilitate access to care, reduce risk for transmission of SARS-CoV-2, conserve scarce medical supplies, and reduce strain on health care capacity and facilities while supporting continuity of care.”

- An article published by the Commonwealth Fund, notes that “tele- mental health has a robust evidence base and numerous studies have demonstrated its effectiveness across a range of modalities (e.g. telephone, videoconference) and mental health concerns (depression, substance use disorders).”

Telehealth and the future of healthcare delivery

Extend the Expansion of Telehealth Services Under the 1135 Waiver Authority

- Concerned that some of the telehealth services expanded by CMS under the 1135 waiver authority are set to expire at the end of the PHE.
- These telehealth services allowed Medicare to pay for office, hospital, and other visits furnished via telehealth at a patient's homes and have expanded access to health care for beneficiaries across the country.
- Used by our members to provide evaluation and management (E/M) services to treat chronic conditions and have been a valuable resource to expand access and coordinate patient care.
- **We believe telehealth services should remain in place for at least two years after the end of the PHE to ensure that our physicians are able to continue to use this modality to enhance patient care.**
- Both the senate and house have introduced legislation that would expand the telehealth services for and additional two years.

Other Recent AC Activities

- **UHC Xolair Administration Policy**
  - The Advocacy Council and College worked with UHC representatives to clarify policy language and an option for physicians to attest to their patient's continuing administration in their offices.

- **Improving Seniors Access to Care Act**
  - We supported legislation to protect patients from unnecessary delays in care by streamlining and standardizing prior authorization in Medicare Advantage plans.

- **Supporting the Continuation of Telemedicine**

- **Pediatric Subspecialty Loan Repayment Program (PSLRP)**
  - We joined AAP and other medical organizations dedicated to improving the health of young children and advocated for and received $25 million in funding in fiscal year 2022. Once enacted, the funding will provide much-needed loan repayment to pediatric subspecialists.

- **Strengthening the Vaccines for Children Program Act of 2021**

2019

USP General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations*

Reprinted from USP 42—NF 37

Links for Supplemental Resources

- Information on USP General Chapter <797>
- USP General Chapter <797> FAQs
- USP General Chapter <797> Education Courses
- Sign up for USP Updates

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.
- Dedicated Allergenic Extracts Compounding Area (AECA)
- BUD (by use date) remains 12 months

USP: Allergenic Extracts Compounding Area (AECA)

- 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

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

- BUD (by use date) remains 12 months

- Large compounders may oppose our separate section

- What happens if I don't participate in USP?

Our Allergen Extract Mixing toolkit – everything you need to implement the new USP 797 rule!

college.acaai.org/extract

- Step by step guides
- Staff competency assessments
- How to implement the new standards webinar
- Allergen Extract Quiz
- FAQs, logs, forms and more

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A day in the life of the Advocacy Council

- The Advocacy Council notified College members after becoming aware of a United HealthCare (UHC) policy change that would require the home administration of Xolair, effective Oct. 1.
- We sent a comment letter that identifies reasons self-administration is not appropriate for all patients.
- We also developed sample talking points and encouraged all College members to join our grassroots effort. Our efforts made a difference.
- UHC responded the next day and explained that providers can attest that self-administration is not appropriate for every patient and that this should be considered on a case-by-case basis.
- They also confirmed that the new policy change was only “specific to UHC commercial plans” and that “coverage policies under UHC MedicareAdvantage and Community Plans **may differ**.”
- As a result of our efforts, UHC agreed to **evaluate revisions** made to the commercial plans policy.
- This is another great example of our advocacy at work.

Check out all our tool kits

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- Allergen Extract Mixing
- Asthma and Allergy Awareness
- Atopic Dermatitis Shared Decision Making
- Biologics
- Chronic Rhinosinusitis with Nasal Polyps
- Coding
- Collections
- Epinephrine
- Human Resources
- Immunotherapy
- Marketing and Patient Materials
- Office based Anaphylaxis
- Patient Satisfaction
- Peanut OIT
- Penicillin
- Practice Parameters and Yardstick
- Practice Profitability
- Prior Authorizations
- Risk and Compliance
- Severe Asthma Shared Decision Making
- Severe Pediatric Asthma Shared Decision Making
- Telehealth

https://college.acaai.org/practice-management/

Advocacy Council Strike Force: May 6-8, 2019

- Held in conjunction with AAN Capitol Hill Day
  - Used shared talking points for both groups.
  - Joined by the Executive Vice president and President of the Academy.
- Appointments with Key decision makers:
  - HHS Secretary Azar's Staff
  - House Energy and Commerce Committee (Majority)
  - Senate Finance Committee (Majority)
  - House Ways and Means Committee (Minority)
  - Senate HELP Committee (Majority)
  - Rep. Morgan Griffith (VA) - Thank you for USP help
  - Rep. Ro Khanna (CA) – Thank you for Food Allergy research funding

Advocacy Council Strike Force: May 6-8, 2019

Focus:

- Patient Access to Specialty Care – Surprise Medical Bills

  (Narrow Networks)
- Physician Focused Payment Models
- Alternative Payment Model(APM) for Patient-Centered Asthma Care

Held in conjunction with AAN Capitol Hill Day

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Allergy & Asthma NETWORK

35TH ANNIVERSARY

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The Advocacy Council is like air-conditioning on a hot summer day in Tennessee - only missed if we're not working!

Thank you for your support!

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Acknowledgements

Allen Meadows, MD FACAAI

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- Questions?

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