Documents for the Record – 4/17/2024

Majority:

- April 16, 2024 – Statement submitted by the American Hospital Association
- April 16, 2024 – Statement submitted by the United Network for Organ Sharing
- April 17, 2024 – Document Submitted by Rep. Carter
- April 17, 2024 – Letter from the Biotechnology Innovation Organization to Administrator Brooks-LaSure and Director Young
- April 17, 2024 – Statement submitted by the American Association of Nurse Anesthesiology President Dru Riddle

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Statement

of the

American Hospital Association

for the

Committee on Energy and Commerce

Subcommittee on Health

of the

U.S. House of Representatives

"Fiscal Year 2025 Department of Health and Human Services Budget"

April 17, 2024

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) writes to you in advance of the April 17 hearing on the President's Fiscal Year (FY) 2025 Health and Human Services' (HHS) budget to share concerns about proposals that would unfairly penalize hospitals and not improve cybersecurity of the entire health care sector.

HOSPITALS AND HEALTH SYSTEMS ARE COMMITTED TO CYBERSECURITY

Hospitals and health systems have invested billions of dollars and taken many steps to protect patients and defend their networks from cyberattacks that can disrupt patient care and erode privacy by the loss of personal health care data. The AHA has long been committed to helping hospitals and health systems with these efforts, working closely with our federal partners, including the FBI, HHS, National Security Council, Cybersecurity and Infrastructure Security Agency, and many others to prevent and mitigate cyberattacks.

As data theft and ransomware attacks targeting health care have increased dramatically over the past several years, the AHA has worked closely with federal agencies and the hospital field to build trusted relationships and channels for the mutual exchange of cyber threat information, risk mitigation practices and resources to implement these practices. The AHA's work in this area was critically important and allowed us to quickly assist members in their response to the recent Change Healthcare cyberattack.

COMMENTS ON CYBERSECURITY PROPOSAL IN FY 2025 BUDGET

Hospitals and health systems are not the primary source of cyber risk exposure facing the health care sector. A review of the top data breaches in 2023 shows that over 95% of the most significant health sector data breaches, defined by those where over 1 million records were exposed, were related to "business associates" and other non-hospital health care entities, including the Centers for Medicare & Medicaid Services (CMS), which had a breach included in the top 20 largest data breaches last year. Any proposals that unfairly focus on one part of the health care sector will ultimately not address cyber risk in a comprehensive, strategic manner.

The AHA supports voluntary consensus-based cybersecurity practices, such as those announced in January by HHS. These cybersecurity performance goals (CPGs) are targeted at defending against the most common tactics used by cyber adversaries to attack health care and related third parties, such as exploitation of known technical vulnerabilities, phishing emails and stolen credentials.

The AHA was meaningfully involved in the development of the CPGs and will continue to work collaboratively with HHS, the Healthcare Sector Coordinating Council and other federal partners to enhance cybersecurity efforts for the entire health care field, including hospitals and health systems, technology providers, payers, pharmacists and other vendors, to ensure we are all protected against the primary source of cyber risk – criminal and nation state-supported cyber adversaries.

The President's FY 2025 budget recommends new penalties for hospitals and health systems for not meeting what the Administration defines as essential cybersecurity practices. Beginning in FY 2029, the Administration proposes to enforce adoption of essential practices with hospitals failing to meet these standards facing penalties of up to 100% of the annual market basket increase and, beginning in FY 2031, potential additional penalties of up to 1% off the base payment. Critical access hospitals that fail to adopt the essential practices would incur a payment reduction of up to 1%, but their total penalty is capped. While it is coupled with funding purported to assist hospitals in defending against cyberattacks, the per hospital benefit would be extremely limited.

The AHA opposes proposals for mandatory cybersecurity requirements being levied on hospitals as if they were at fault for the success of hackers in perpetrating a crime. The now well-documented source of cybersecurity risk in the health care sector, including the Change Healthcare cyberattack, is from vulnerabilities in third-party technology, not hospitals' primary systems. No organization, including

federal agencies, is or can be immune from cyberattacks. Imposing fines or cutting Medicare payments would diminish hospital resources needed to combat cybercrime and would be counterproductive to our shared goal of preventing cyberattacks.

To make meaningful progress in the war on cybercrime, Congress and the Administration should focus on the entire health care sector and not just hospitals. Furthermore, for any defensive strategy imposed on the health care sector, Congress should call on federal agencies to protect hospitals and health systems — and the patients they care for — by deploying a strong and sustained offensive cyber strategy to combat this ongoing and unresolved national security threat. Health care is a top critical infrastructure sector with direct impact to public health and safety and must be protected. Any cyberattack on the health care sector that disrupts or delays patient care creates a risk to patient safety and crosses the line from an economic crime to a threat-to-life crime. These attacks should be aggressively pursued and prosecuted as such by the federal government. We use the term “prosecuted” in all sense of the definition related to the totality of the government’s capabilities and authorities, including intelligence and military authorities.

Imposing swift and certain consequences upon cyber adversaries, who are often provided safe harbor in non-cooperative foreign jurisdictions, such as Russia, China, Iran and North Korea, is essential to reducing the cyber threats targeting health care and the nation.

CONCLUSION

The cybersecurity proposal put forward in the President’s FY 2025 budget that would penalize hospitals is misguided and will not improve the overall cybersecurity posture of the health care sector. Imposing fines or cutting Medicare payments will only weaken the collective cyber defense capability of the entire health sector. The penalties described in this proposal would only serve to deplete the resources needed to combat cybercrime and would be counterproductive to our shared goal of preventing cyberattacks. Hospitals are just one piece of the health care sector and hospitals alone cannot control the cyber risks for the entire sector. To make meaningful progress in the war on cybercrime, AHA urges Congress to enact policies that address cybersecurity sector-wide and not force hospitals to shoulder responsibility for systems outside of their control.

Statement of the United Network for Organ Sharing on the President's FY 2025 Budget Request for the Health Resource Services Administration (HRSA)

The United Network for Organ Sharing (UNOS) strongly supports the President's Fiscal Year (FY) 2025 budget request of $67 million to fund the Health Resources and Services Administration (HRSA) Organ Procurement and Transplant Network Modernization Initiative (OPTN), the agency's plan to modernize and strengthen the organ donation and transplant system.

This funding is critical to implement The Securing the U.S. Organ Procurement and Transplantation Network Act (Pub. Law. 118-140). This landmark legislation enacted in 2023 to modernize the country's organ transplant system represents the first major reforms to the system in 40 years. UNOS supports HRSA's modernization initiative, including allowing multiple contractors to manage and supervise various functions of the system. With our 40 years of experience operating the nation's Organ Procurement and Transplantation Network, UNOS knows how unique and complicated the process of organ donation and transplant is. Transforming the system will not be simple, and it is imperative that HRSA has enough resources to be successful.

UNOS continues to work with the organ donation and transplant community to drive improvement and make the system as efficient and effective as possible to save more lives.

In 2023, the organ donation and transplant community worked together to achieve:

- More than 16,000 deceased organ donors, a new annual record and a continuation of a 13-year annual-record trend
- More than 46,000 organ transplants performed, continuing annual record-setting trend
- More than 10,000 transplant recipients were Black, non-Hispanic
- More than 10,000 liver transplants performed for the first time
- More than 3,000 lung transplants performed for the first time
- New annual records also set for kidney and heart transplants

But there is more that the community can and must do to serve the thousands of patients still waiting for a lifesaving organ. Transformation and modernization are necessary to continue to improve the system and ensure that we continue to save lives through donation and transplant. As we look ahead to Fiscal Year 2025 and beyond, we should pause to recognize that we are at an inflection point in this community. We have the opportunity to not just embrace change but also to ignite transformation, and doing so will require additional federal investment.

UNOS is committed to working with Congress and the administration to carry out system improvements and reforms for the benefit of all donors, candidates, recipients, families, and caregivers.

Looking to the future and the new multi-vendor approach to OPTN work, it is imperative that HRSA ensures robust competition for the contracts and plans for adequate staff to be able to effectively coordinate and oversee this new arrangement. HRSA will need the resources to oversee this unique and intricate part of the health care system with multiple vendors providing services.

We encourage Congress to provide the administration with the request of $67 million in FY 2025 to fund the Organ Procurement and Transplant Network Modernization Initiative within HRSA to create a system that can save even more lives through the gift of life.

Accumulator Practices Harm Patients — Coad Family Story

Posted on February 7, 2024

Macy Coad was diagnosed with Juvenile Arthritis at 16 months old. Today, at 17, she manages her disease with biologics and other treatments. The family was handling the cost of the medications with the help of a copay assistance program. Then suddenly they were hit with a nearly $2,000 fee for one month's medication. Their pharmacy benefit manager for their insurance had instituted a copay accumulator policy which stopped their assistance program payment from counting towards their out-of-pocket cost. Watch the video and hear Gerica Coad, Macy's mother, explain what happened and how much a copay accumulator policy can hurt patients and their families.

Learn more about copay accumulators on the CCPA website or the CCPA blog post *Copay Accumulator Adjustment Program Significantly Impact Patient Financial Burden*. You can also visit www.MyPatientRight.org for more information.

Biotechnology Innovation Organization
1201 New York Ave, NW
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April 8, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

The Honorable Shalanda Young
Director
Office of Management & Budget
725 17th Street, N.W.
Washington, D.C. 20503

Dear Administrator Brooks-LaSure & Director Young:

We, the undersigned, are writing to express our strong concern with a proposed update to the Medicaid Drug Rebate Program (MDRP). If finalized in its current form, the proposed rule (CMS-2434-P) would impose significant costs to the government and industry and create extensive barriers to patient access to existing innovative therapies and to developing new cures for Medicaid enrollees.[1] As a result, it will deny some of the nation's most vulnerable patients access to the state-of-the-art medical care they deserve, both now and in the future.

We are deeply committed to advancing medical science in ways that prevent suffering and save lives -- particularly for the less advantaged populations Medicaid was created to serve. But the proposed rule would make our continued participation more difficult, while leaving patients who rely on Medicaid profoundly worse off.

Small- and medium-sized biopharmaceutical companies like ours already face severe headwinds in bringing new therapies and cures to patients. Nearly every aspect of the drug development process -- from identifying potential new therapies to securing venture capital and organizing clinical trials -- is fraught with uncertainty, the risk of which translates directly into higher costs. And the overwhelming majority of candidate drugs we pursue ultimately fail, some only after years (or decades) of research and tens of millions of dollars.[2]

What drives us to overcome these challenges and endure repeated failures is the knowledge that, when we do succeed, our work can save lives and improve health on a massive scale. Our desire to serve our nation's less advantaged populations is central to this mission.

The Medicaid Drug Rebate Program has helped bring hundreds of revolutionary therapies to underserved and marginalized patients while maintaining incentives for continued research into new treatments and cures. Unfortunately, the proposed rule would put this carefully struck balance in jeopardy.

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[1] https://www.cms.gov/newsroom/fact-sheets/misclassification-drugs-program-administration-and-program-integrity-updates-under-medicaid-drug

[2] https://www.nature.com/articles/nrd.2016.136

Of particular concern is the proposed rule's new definition of "best price." Current law defines this as the lowest or "best" price available to any entity in the drug supply chain, be it a wholesaler, insurer, nonprofit, or government entity.[3] The proposed rule would fundamentally change how this best price is determined -- and in a way that makes it vastly more difficult for small- and medium-sized firms like ours to serve Medicaid patients.

Specifically, the proposed rule mandates that companies aggregate or "stack" any discounts or rebates provided to various entities who encounter the drug unit in the drug supply chain in order to calculate the best price.[4] This task is not only daunting. It is, at present, impossible to implement.

No system exists today that is capable of tracking price concessions given to all entities that purchase or cover a given drug across the supply chain. Such a system would require companies to collect, analyze, and publicize data from potentially hundreds of different stakeholders, which could strain the resources of even the largest pharmaceutical firms, let alone biotech start-ups with less than a dozen employees. Aggregated discount calculations off by a single cent could mean that firms are technically noncompliant with federal policy.

In addition to operational impediments, the rule's overall cost to our companies would be very significant and could make ongoing participation untenable. It could thus dramatically reduce the number of drugs available to vulnerable patients and seniors. In so doing, it further could create perverse incentives, decreasing the potential that companies would offer rebates beyond the statutory minimum Medicaid Drug Rebate for fear of not being able to track such discounts and report them accurately under the new rule. This could lead to further market consolidation and higher ultimate costs for entities like providers and hospitals.

By increasing both the costs and risks involved in serving underprivileged patients through the Medicaid Rebate Program, the rule would discourage investment in medicines from which these vulnerable populations are most likely to benefit. The result would be less innovation, fewer new cures, and worse health outcomes for disadvantaged groups over the long term.

Those of us who are pursuing innovative cell and gene therapies are also concerned with CMS' new definition of covered outpatient drugs.[5] Many of our companies have worked with states under their existing regulatory authority to establish a reimbursement system for cell and gene therapies that is "site neutral" (i.e., ensuring reimbursement policy does not effectively dictate clinical decision making regarding the best setting of care for an individual patient). This solution both provides for adequate hospital reimbursement and ensures States recoup the mandatory Medicaid Drug Rebate on innovative therapies.

The proposed definitional change would upend this existing solution that is working well. Specifically, it would remove the requirement that inpatient-administered therapies be paid for

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[3] https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/view/footnotes/#footnote-438418-7

[4] https://www.cms.gov/newsroom/fact-sheets/misclassification-drugs-program-administration-and-program-integrity-updates-under-medicaid-drug

[5] https://www.cms.gov/newsroom/fact-sheets/misclassification-drugs-program-administration-and-program-integrity-updates-under-medicaid-drug

separately from the reimbursement for the underlying hospital stay in order to qualify for the Medicaid Drug Rebate.[6] This would be a significant departure from many years of precedent and would endanger hospitals' ability to provide these potentially curative medicines.

As a result of this proposed change, many states may no longer pursue separate reimbursement for certain inpatient therapies, which could, in turn, lead to significant financial losses for hospitals serving low-income populations and threaten patient access to cutting-edge cell and gene therapies. The redefinition could also discourage ongoing investment into high-potential research and development.

Our concerns about negative impacts on patient access extend to another element of the proposed rule: CMS' proposal to implement a new "price verification" survey for certain "high cost" drugs. The proposed survey – which is without any legal grounding – has a troubling, narrow focus on cost-based inputs. It ignores critical areas such as patient outcomes, patient experience, and caregiver impact. CMS should not move forward with implementing this survey and instead, the Agency should shift its mindset to one of identifying innovative payment and contracting approaches that will promote access for vulnerable patients in Medicaid including cell and gene therapies.

Finally, it is imperative that CMS not view proposed changes to Medicaid in a vacuum, but in the broader context of the many other recent changes to federal healthcare programs. The Inflation Reduction Act's recent reforms to Medicare Part D and ongoing negotiations with Part D plan sponsors and pharmacy benefit managers, for instance, have added to the cost of providing Medicare beneficiaries with access to the latest therapies from companies like ours.[7] As a result, many of our firms may soon lack the resources to offer supplemental rebates to states through Medicaid, thus putting patient access at risk.

We urge you to reconsider these proposals and allow us to continue in our shared mission of promoting health equity and safeguarding the health of vulnerable patients across the country.

Sincerely,

John Crowley
President & CEO
Biotechnology Innovation Organization

Ted Love, MD
Chairman, ARTBIO, Inc
Chair, BIO Board of Directors

Acadia Pharmaceuticals

Ron Cohen
President & CEO
Acorda Therapeutic, Inc.

Alkermes

Alnylam Pharmaceuticals

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[6] https://www.cms.gov/newsroom/fact-sheets/misclassification-drugs-program-administration-and-program-integrity-updates-under-medicaid-drug#:~:text=Enhancing%20States%E2%80%99%20Abilities%20to%20Manage%20Medicaid%20Drug%20Spending

[7] https://www.milliman.com/en/insight/part-d-redesign-under-ira-potential-financial-ramifications

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American Association of
NURSE ANESTHESIOLOGY

Written Statement for the Record by:

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House Energy and Commerce Committee

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April 17, 2024

Background on AANA and CRNAs

Chair Rodgers, Ranking Member Pallone, and Members of the Committee, thank you for the opportunity to offer this statement for the record. The American Association of Nurse Anesthesiology (AANA) is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists, with membership that includes more than 61,000 CRNAs and student nurse anesthetists representing over 85 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who provide anesthesia, acute, chronic, and interventional pain management services. In some states, CRNAs are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities.

AANA applauds the Committee's continued oversight of the ways the Department of Health and Human Services (HHS) spends its funds to ensure the highest quality of healthcare for our nation. This hearing is an important opportunity to address the rising costs of providing healthcare across the United States, and how we can take meaningful steps to alleviate that cost. To provide the best possible care, while saving our taxpayers from shouldering the increasing costs, HHS should remove unnecessary barriers to care and promulgate impactful regulations to enforce provider nondiscrimination. These steps will ensure that our nation's patients have access to the highest-quality, most cost-effective care America can offer.

CRNAs are involved in every aspect of providing anesthesia services, including pre-anesthesia patient assessment, obtaining informed consent for anesthesia administration, developing a plan for anesthesia administration, administering the anesthetic, monitoring the patient's vital signs, and managing the patient throughout the surgery. Our members provide anesthesia for a wide variety of surgical cases and, in some states, are the sole anesthesia provider in nearly all rural hospitals, affording these facilities obstetrical, surgical, trauma stabilization, and pain management capabilities. Nurse anesthesia predominates in Veterans Hospitals and in the U.S. Armed Services, the latter of which has granted CRNAs full practice rights. CRNAs work effectively in every setting in which anesthesia is delivered: hospital surgical suites; obstetric delivery rooms; ambulatory surgical centers; pain management facilities; as well as the offices of dentists, podiatrists, and all types of specialty surgeons.

Numerous peer-reviewed studies have shown that CRNAs are safe, high-quality, and cost-effective anesthesia professionals who should practice to the full extent of the education and abilities. A 2016 study published in the journal *Medical Care* found that CRNA-only anesthesia care was no different that physician-only anesthesia care in terms of quality of care and health

outcomes.[1] This study builds on previous works that have shown time and time again that CRNAs provide the same high-quality healthcare that physician anesthesiologists provide.[2, 3]

Further, CRNAs play an integral role in assuring that rural America has access to critical anesthesia services, often serving as the sole anesthesia provider in rural hospitals, affording these facilities the capability to provide many procedures that would otherwise leave patients hours away from medical care. A 2020 study published in *The Journal of Rural Health* found CRNAs to be the most common anesthesia provider in rural hospitals due to their "strong, diverse skills sets," that allowed high levels of autonomy.[4] Of particular importance to the implementation of public benefit programs in the U.S., the study also showed that compared with anesthesiologists, CRNAs are more likely to work in areas with lower median incomes and larger populations of citizens who are unemployed, uninsured, and/or Medicaid beneficiaries.[5]

Finally, studies have also shown that CRNAs "are less costly to train than anesthesiologists," and "can perform the same set of anesthesia services, including relatively rare and difficult procedures," as their physician anesthesiologist peers.[6] Given the reality that CRNAs provide the same high-quality care as other anesthesia providers, serve under-resourced communities, and do so at a significant cost-savings when compared to physician anesthesiologist, it is imperative that barriers to accessing CRNA care are eliminated. HHS must eliminate unnecessary physician supervision rules and promulgate a meaningful, enforceable provider nondiscrimination rule.

CRNA Supervision: At What Cost?

Currently, regulations from the Centers for Medicare and Medicaid Services (CMS) create cumbersome, costly impediments to care. Under the current requirements, or Conditions of Coverage and Conditions of Participation, facilities are subject to the unnecessary and costly requirement for physician supervision of CRNA services for the provision of anesthesia care.

There is no evidence that physician supervision of CRNAs improves patient safety or quality of care. In fact, the aforementioned studies show that health outcomes are identical. A comprehensive literature review published in 2019 found that "**the strong safety record of**

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[1] Negrusa, Brighita PhD; Hogan, Paul F. MS; Warner, John T. PhD; Schroeder, Caryl H. BA; Pang, Bo MS. Scope of Practice Laws and Anesthesia Complications: No Measurable Impact of Certified Registered Nurse Anesthetist Expanded Scope of Practice on Anesthesia-related Complications. Medical Care 54(10):p 913-920, October 2016. | DOI: 10.1097/MLR.0000000000000554

[2] Dulisse, B., & Cromwell, J. (2010). No harm found when nurse anesthetists work without supervision by physicians. *Health Affairs*, *29*(8), 1469–1475. https://doi.org/10.1377/hlthaff.2008.0966

[3] Hoyem RL, Quraishi JA, Jordan L, Wiltse Nicely KL. Advocacy, Research, and Anesthesia Practice Models: Key Studies of Safety and Cost-Effectiveness. Policy Polit Nurs Pract. 2019 Nov;20(4):193-204. doi: 10.1177/1527154419874410. Epub 2019 Sep 11. PMID: 31510877.

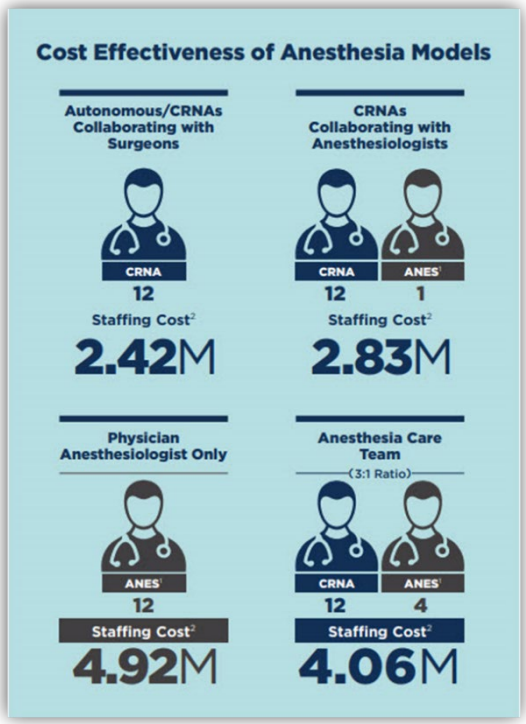
[4] Cohen, C., Baird, M., Koirola, N., Kandrack, R., & Martsolf, G. (2020). The surgical and anesthesia workforce and provision of surgical services in rural communities: A mixed-methods examination. The Journal of Rural Health, 37(1), 45–54. https://doi.org/10.1111/jrh.12417

[5] Liao CJ, Quraishi JA, Jordan LM. Geographical Imbalance of Anesthesia Providers and its Impact On the Uninsured and Vulnerable Populations. Nurs Econ. 2015 Sep-Oct;33(5):263-70. PMID: 26625579.

[6] Hogan PF, Seifert RF, Moore CS, Simonson BE. Cost effectiveness analysis of anesthesia providers. Nurs Econ. 2010 May-Jun;28(3):159-69. PMID: 20672538.

anesthesia in general and CRNAs in particular suggest that politics and professional interests are the main drivers of supervision policy in anesthesia delivery."[7]

As of the time of this hearing, 24 states have already opted-out of CMS' supervision requirements for CRNAs. Studies have repeatedly shown that there is no evidence "that opting out of the oversight requirement resulted in increased inpatient deaths or complications."[8] The same study recommended that "CMS allow [CRNAs] in **every state** to work without the supervision of a surgeon or anesthesiologist."[9]



Comparing various methods of anesthesia delivery, an autonomous CRNA collaborating with a surgeon is the most cost-effective model for anesthesia delivery. Current trends in the QZ modifier, which is utilized when a CRNA is billing for anesthesia without supervision, have shown a steady increase in the utilization of this billing modifier, implying an increase in CRNA autonomous practice. The anesthesia care team model, of 1:3 supervision is one of the most expensive anesthesia delivery models possible. Allowing for autonomous practice by CRNAs allows facilities the flexibility to choose a model that meets their needs and helps to keep costs down. Patients and taxpayers deserve better than our nation's current inefficient anesthesia delivery models.

Provider Non-Discrimination

We remain ready to work with the Committee, HHS, and their respective staffs to finally deliver a rule implementing the provider nondiscrimination provision in the *Consolidated Appropriations Act, 2021* (PL 116-260).

This provision has its roots in the *Patient Protection and Affordable Care Act*, in which Section 1201 prohibited health plans from discriminating against qualified licensed healthcare professionals, such as CRNAs, solely on the basis of their licensure. However, no regulation has been issued in the decade since this law took effect—January, 2014—and no real enforcement mechanism exists, allowing health plans to issue discriminatory policies against CRNAs and other non-physician providers. The inaction following the implementation of the law lead to the

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[7] Hoyem RL, Quraishi JA, Jordan L, Wiltse Nicely KL. Advocacy, Research, and Anesthesia Practice Models: Key Studies of Safety and Cost-Effectiveness. Policy Polit Nurs Pract. 2019 Nov;20(4):193-204. doi: 10.1177/1527154419874410. Epub 2019 Sep 11. PMID: 31510877.

[8] Dulisse, B., & Cromwell, J. (2010a). No harm found when nurse anesthetists work without supervision by physicians. *Health Affairs*, *29*(8), 1469–1475. https://doi.org/10.1377/hlthaff.2008.0966

[9] Op. Cit.

inclusion of another provision, this time in the *Consolidated Appropriations Act, 2021*, which directed HHS, the Department of the Treasury, and the Department of Labor to promulgate an interagency rulemaking implementing protections against provider discrimination by January 1, 2022. We are now more than two years beyond that deadline, leaving healthcare providers vulnerable to discriminatory policies employed by health plans.

The AANA believes it is discrimination if health plans or health insurers have a policy that reimburses differently for the same services provided by different provider types while achieving the same high quality outcomes**.** While health plans might believe this is a cost-effective way to save money and lower health care costs, this would direct cases to more expensive providers, such as anesthesiologists, leading to impaired access, increased costs and lower quality of care. Paying one qualified provider type a higher rate than another for providing the same high-quality service offers a powerful incentive to increase healthcare costs without improving healthcare quality or access, by helping to steer healthcare delivery to more expensive providers. The AANA also interprets the provider nondiscrimination provision to mean that if a health plan or health insurer network offers a specific covered service, they should include in their network all types of providers who can safely provide that service and should not refuse to contract based on licensure alone.

Most recently, the American Bar Association (ABA) weighed in on the issue, citing the need for promulgation of rulemaking to stop insurers from discriminating, writing "Notwithstanding that this has been the law for the past 14 years, insurance companies and plans, including ERISA plans, continue to discriminate on providers practicing within the full scope of practice."[10] The ABA also noted that this type of discrimination goes against recent efforts to shift toward performance and quality based reimbursement.

Proper implementation of the provider nondiscrimination law is crucial because health plans have latitude to determine the quantity, type, and geographic location of healthcare professionals they need to ensure availability of healthcare benefits to their enrollees. However, when health plans organize their healthcare delivery in such a way that they discriminate against whole classes of qualified licensed healthcare professionals by licensure, for example, by prohibiting reimbursement for anesthesia and pain management services provided by CRNAs, patient access to care is impaired, consumer choice suffers, and healthcare costs climb for lack of competition. Additionally, such discrimination provides incentives for the use of higher-cost providers without improving quality or access to care. Promoting nondiscrimination encourages consumers to be able to choose anesthesia care from qualified, licensed healthcare professionals such as CRNAs who perform the same services to the same high level of quality as other qualified providers. Moreover, promulgation of a regulation on provider nondiscrimination would allow CRNAs to fully utilize their education and training to enhance the patient care team model and work collaboratively with anesthesiologists as equal partners in anesthesia delivery for surgery, labor and delivery, trauma stabilization, and chronic pain management.

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[10] American Bar Association. March 29, 2024. *Opinion: Provider Non-Discrimination Law Continues To Be Violated By Insurance Companies.* https://www.americanbar.org/groups/health_law/section-news/2024/march/opinion-provider-non-discrimination-law-continues-to-be-violated-by-insurance-companies/

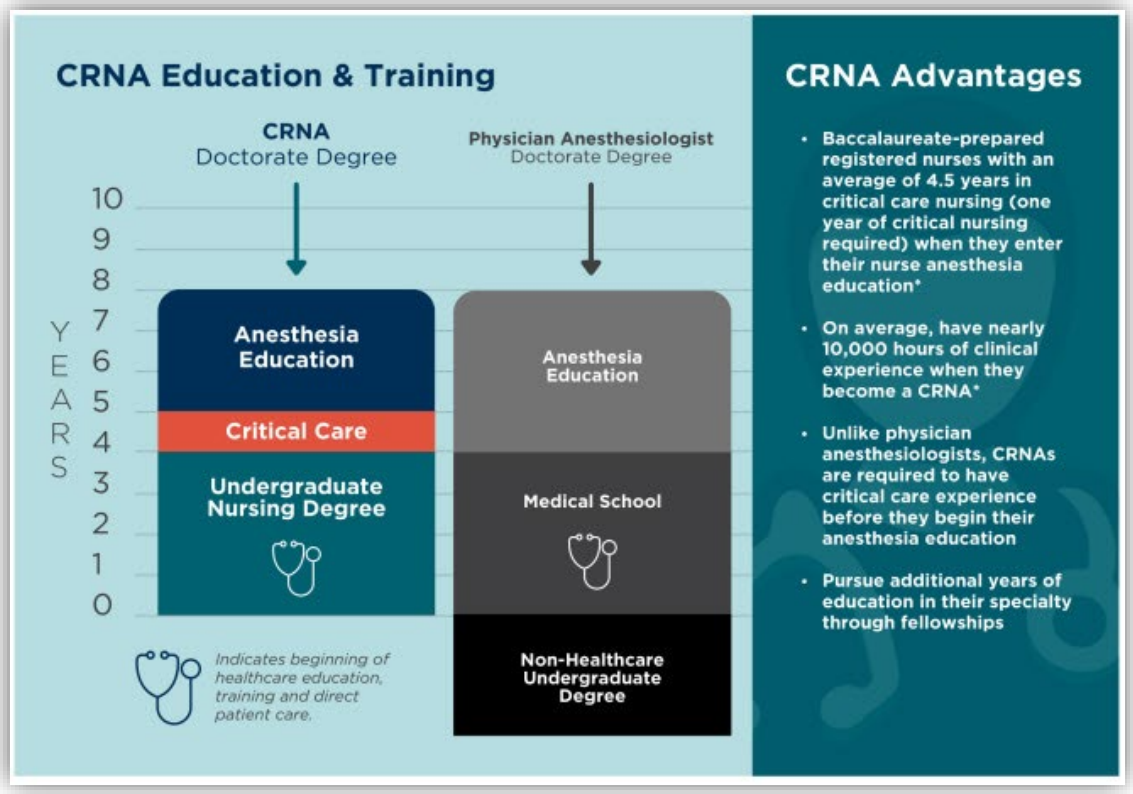
The Unified Agenda currently lists an August 2024 deadline for the joint rulemaking process. In order to promote access to healthcare, consumer choice, reduce healthcare costs through competition, and provide high-quality healthcare, we urge the Committee to work with HHS to finalize this rulemaking.

CRNA Safety and Outcomes

The evidence is overwhelming that CRNA independent practice is just as safe as the anesthesia care provided under supervision or by our physician anesthesiologists colleagues. In a VA commissioned from Temple University, it was found that "studies have found that CRNAs who had an expanded scope of practice did not have worse patient outcomes, complications, or mortality when compared to anesthesiologists."[11] A peer reviewed study published in the Journal of Medicare Care in 2016 looked at anesthesia related complications for CRNA only, anesthesiologist only, and a team-based approach and found there were no differences in complication rates based on delivery model.[12] This corroborates an earlier peer reviewed study published in Health Affairs in 2010 that looked at the differences in outcomes in states that had opted out of Medicare's supervision requirement for CRNAs were no different than outcomes in states that maintained supervision.[13] A comprehensive review completed by the Cochrane Library in 2014 further reinforced these finding, when it reviewed the literature on anesthesia staffing and found that there could be no definitive statement can be made about the superiority of anesthesia delivery models.

Some low-quality studies have purported to claim that CRNAs providing anesthesia without supervision negatively affects outcomes. A 25-year-old study that was not published in an outside peer-reviewed Journal, but rather in the Journal run by the American Society of Anesthesiologists, has major methodological issues that lead the Centers for Medicare and Medicaid to dismiss the study as too flawed to be used, stating, "One cannot use this analysis (Silber) to make conclusions about CRNA performance with or without physician supervision." This study looked at outcomes for 30-days post operative period, which is well outside the 48-hour period for anesthesia related complications.

[11] Baumle, op. cit.
[12] "Scope of Practice Laws and Anesthesia Complications" (Negrusa, Hogan, Warner, Schroeder, and Pang, 2016). https://journals.lww.com/lww-medicalcare/abstract/2016/10000/scope_of_practice_laws_and_anesthesia.4.aspx
[13] "No Harm Found When Nurse Anesthetists Work Without Supervision By Physicians" (Dulisse and Cromwell, 2010). https://www healthaffairs.org/doi/abs/10.1377/hlthaff.2008.0966?journalCode=hlthaff



Conclusion

We would like to thank the Committee for their attention to HHS' budget, it is of the utmost importance to highlight the barriers to healthcare that exist, driving up costs and wait times. We urge the Committee to work with HHS to implement changes to physician supervision and promulgation of a long overdue provider nondiscrimination rule in order to unlock affordable, high-quality healthcare for Americans in all areas. CRNAs outsized importance underserviced communities, such as rural and low-income areas, only compounds the deleterious impacts that current barriers have on our nation's healthcare system. We look forward to working with the Committee, HHS, and their respective staffs to accomplish these goals and deliver for our patients and taxpayers. If you have any questions, or would like to reach out to AANA for additional information, please contact Matthew Thackston [redacted] or Kristina Weger [redacted].