COLLEGE of AMERICAN PATHOLOGISTS

Regulatory Advocacy at the Local, State & Federal Levels

Maintaining Coordination and Advancing Your Goals

Elizabeth Fassbender, JD, Director,
Economic and Regulatory Affairs

April 22, 2025

Regulatory Advocacy

- “The crucial intermediate process of rulemaking stands between the enactment of a law by Congress and the realization of the goals that both Congress and the people it represents seek to achieve by that law” *
- Between 2019 and 2020, Congress enacted 344 laws, while agencies completed 5,838 rulemakings during that same time

*Cornelius M. Kerwin, Rulemaking: How Government Agencies Write Law and Make Public Policy, 4th ed., (Washington: CQ Press, 2011), p. 2.

Regulatory and Legislative Coordination

- Ensure same strategic goal, unified position/priorities
- Share public comments, testimony, op-eds, talking points, and briefings across all teams
- Establish regular cross-team check ins
- Host a “lunch and learn” or similar event to increase understanding

Regulatory and Legislative Coordination

- **Starts with the legislation…**
  - **What does the law say?**
  - **Where can you influence?**

"(3) TREATMENT OF BATCHING OF ITEMS AND SERVICES.—

"(A) IN GENERAL.—Under the IDR process, the Secretary shall specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination by an entity for purposes of encouraging the efficiency (including minimizing costs) of the IDR process. Such

We also stress that regulations should clarify what happens in the situation where there is no response from the health plan to start the open negotiation period, either initial payment or notice of denial of payment. For example, we support clarification that a health plan's failure to respond within 30 days after the bill has been submitted should be deemed a notice of denial for purposes of the IDR process, and the provider can then initiate the open negotiation period

2. Batching claims – the ability for providers to batch together claims (allowing "multiple qualified IDR dispute items and services" to be "considered jointly as part of a single determination by an entity") was an important provision included in the *No Surprises Act*, which ensures an equitable and accessible IDR system, while also encouraging efficiency and minimizing costs. Items and services may be batched if (1) furnished by the same provider or facility; (2) involving the same group health plan or insurance issuer; (3) such items/services are related to the treatment of a similar condition; and (4) such items and services were furnished during the same 30-day period. An alternative period of time may be determined by the Secretary, for use in limited situations, such as by the consent of the parties or in the case of low-volume items and services.

First, we strongly encourage the formulation of longer, alternative periods of time in the cases of low-volume services or by consent of the parties. Especially for pathology services, which often have lower reimbursement rates, any flexibility that

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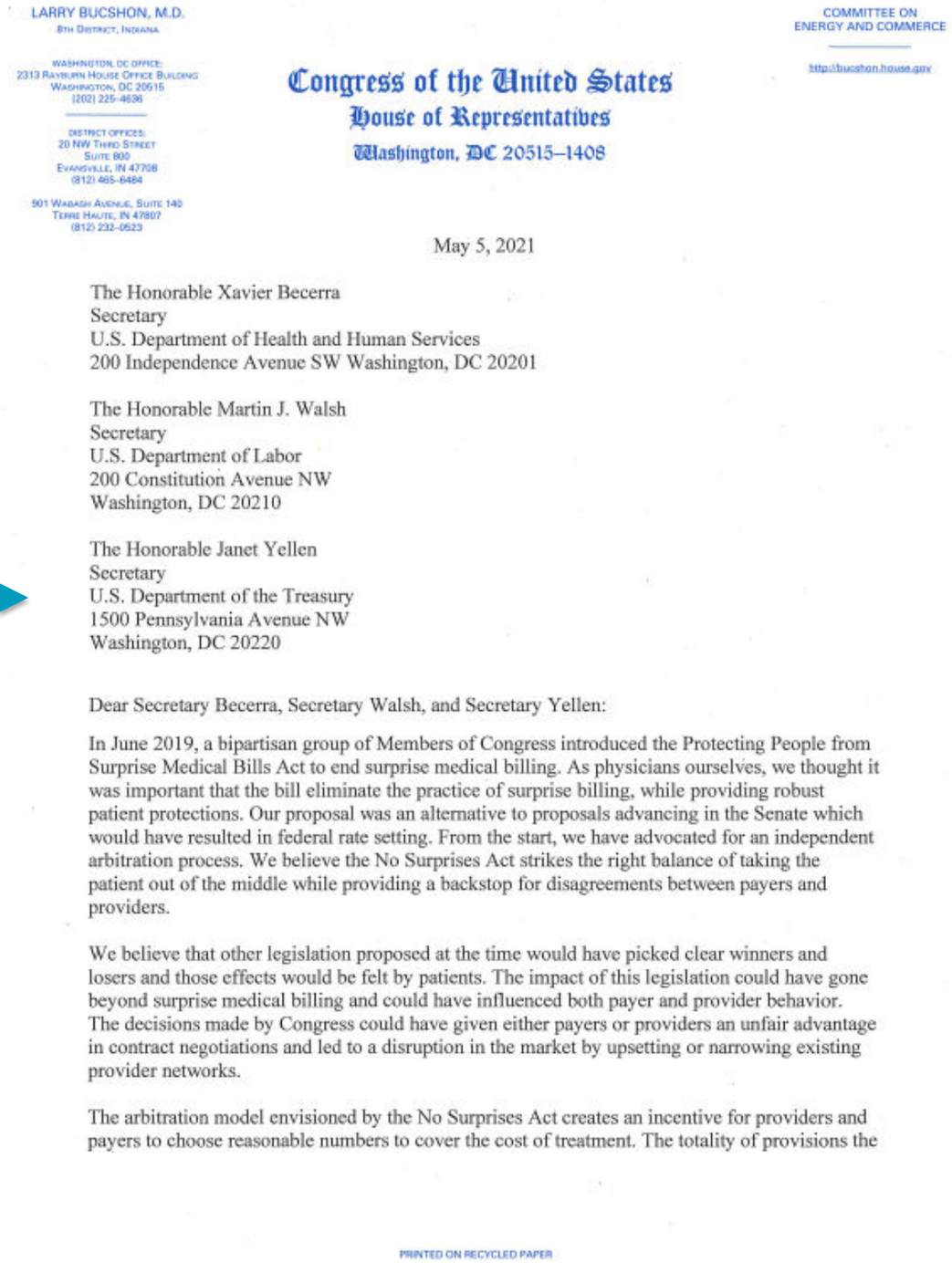
Regulatory and Legislative Coordination

- **Starts with the legislation…**
  - **What does the law say?**
  - **Where can you influence?**
  - **What did legislators intend?**



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http://bucshon.house.gov

Congress of the United States
House of Representatives
Washington, DC 20515–1408

May 5, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW Washington, DC 20201

The Honorable Martin J. Walsh
Secretary
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

The Honorable Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

Dear Secretary Becerra, Secretary Walsh, and Secretary Yellen:

In June 2019, a bipartisan group of Members of Congress introduced the Protecting People from Surprise Medical Bills Act to end surprise medical billing. As physicians ourselves, we thought it was important that the bill eliminate the practice of surprise billing, while providing robust patient protections. Our proposal was an alternative to proposals advancing in the Senate which would have resulted in federal rate setting. From the start, we have advocated for an independent arbitration process. We believe the No Surprises Act strikes the right balance of taking the patient out of the middle while providing a backstop for disagreements between payers and providers.

We believe that other legislation proposed at the time would have picked clear winners and losers and those effects would be felt by patients. The impact of this legislation could have gone beyond surprise medical billing and could have influenced both payer and provider behavior. The decisions made by Congress could have given either payers or providers an unfair advantage in contract negotiations and led to a disruption in the market by upsetting or narrowing existing provider networks.

The arbitration model envisioned by the No Surprises Act creates an incentive for providers and payers to choose reasonable numbers to cover the cost of treatment. The totality of provisions the

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Regulatory and Legislative Coordination

- **Pre-rulemaking advocacy**
  - **Anticipate areas of concern – be proactive**
  - **Provide initial recommendations, solutions**
  - **Meet with agency officials**

COLLEGE of AMERICAN PATHOLOGISTS

May 13, 2021

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Becerra:

The College of American Pathologists (CAP) understands that the Department of Health and Human services (HHS), together with other agencies of jurisdiction, has begun the process for implementing the recently-enacted *No Surprises Act*. While waiting for rulemaking, we write to provide our initial recommendations, which we believe will further safeguard patients from surprise expenses while appropriately balancing disputes between our members and insurers. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

The CAP worked closely with Congress and other stakeholders in the development of the *No Surprises Act*, and we have continually called for protections that keep patients out of the middle of billing disputes. While sometimes described as providing an "ancillary service," pathologists provide a full range of services critical to patient care. For example, pathologists direct clinical and anatomic pathology laboratory services and serve as the expert laboratory consultants to other physicians and hospital leadership; this is in addition to triaging and interpreting biopsies, and evaluating surgical, cytology, and autopsy specimens. Clinical pathology services include development, approval, and evaluation of appropriate test methods, pre- and post-analytical oversight, and direct involvement with technologists and clinical colleagues to ensure prioritization and proper response to test results. During the COVID-19 crisis, pathologists in hospitals and laboratories around the country have been responsible for developing and/or selecting new test methodologies, validating and approving testing for patient use, and expanding the testing capabilities of the communities they serve to meet emergent needs. The influence of all these pathology services on clinical decision-making is pervasive and constitutes a critical infrastructure and foundation for appropriate care.

Without argument, the COVID-19 pandemic has shaken and challenged every health care system and organization. What has remained the same for health care providers is our unwavering commitment to care for our patients and communities. Today more than ever, patients should not be financially penalized for the failure of health insurance plans to establish adequate in-network access to hospital-based physician specialties. Yet, health insurance plans are increasingly relying on narrow and often inadequate networks of contracted physicians, hospitals, and other providers in order to shift medically necessary health care costs onto their enrollees. Even now, health plans are finding ways to circumvent the protections provided in the *No Surprises Act* by subjecting patients to the full payment for services received at in-network, but non-designated" facilities. Strong regulations are needed to prevent health plan manipulation and gaming that will hurt patients, while ensuring robust oversight and audit/complaint processes.

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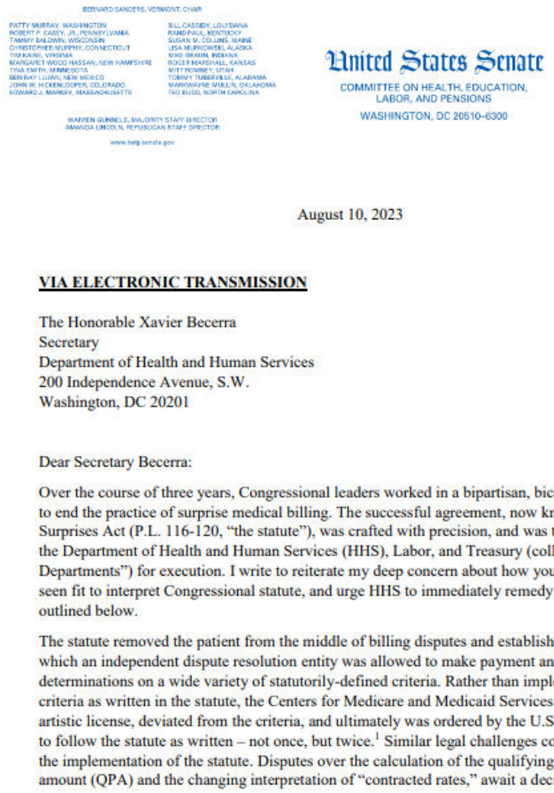
Regulatory and Legislative Coordination

- **Rulemaking process**
  - **Public comment periods – write, submit, and share broadly**
  - **Members or congressional staff can influence ongoing agency rulemakings by communicating their views and preferences directly to the agency**
  - **Know what you'll look for in final rule, be ready to respond**
  - **Continue communication**

Regulatory and Legislative Coordination

- **Regulations and oversight**
  - **How can Congress help?**
  - **Informal communication/questions, hearings, investigations**
    - **Submit statement for record**



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United States Senate
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510–6300

August 10, 2023

VIA ELECTRONIC TRANSMISSION

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Becerra:

Over the course of three years, Congressional leaders worked in a bipartisan, bicameral manner to end the practice of surprise medical billing. The successful agreement, now known as the No Surprises Act (P.L. 116-120, "the statute"), was crafted with precision, and was transmitted to the Department of Health and Human Services (HHS), Labor, and Treasury (collectively "the Departments") for execution. I write to reiterate my deep concern about how your agency has seen fit to interpret Congressional statute, and urge HHS to immediately remedy the issues outlined below.

The statute removed the patient from the middle of billing disputes and established a system in which an independent dispute resolution entity was allowed to make payment and value determinations on a wide variety of statutorily-defined criteria. Rather than implement the criteria as written in the statute, the Centers for Medicare and Medicaid Services (CMS) took artistic license, deviated from the criteria, and ultimately was ordered by the U.S. District Court to follow the statute as written – not once, but twice.[1] Similar legal challenges continue to plague the implementation of the statute. Disputes over the calculation of the qualifying payment amount (QPA) and the changing interpretation of "contracted rates," await a decision while other

Patients Pay the Price for Insurance Companies Kicking Doctors Off Their Networks

Chairman Smith (MO-08) pointed out the flawed implementation of the No Surprises Act has led to doctors and hospitals being removed from insurance networks leaving medical providers, especially those in rural communities, to reduce hours and staff available to care for patients.

Regulatory and Legislative Coordination

- **Regulations and oversight**
  - **Legislation!**

We commend the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services together with the Department of the Treasury and the Department of Labor (the Departments) for their openness in hearing stakeholder concerns and for including important improvements to the IDR process in these proposed rules. We continue to strongly support the protections that keep patients out of the middle of billing disputes. However, as we have previously explained, our members have reported significant difficulties in resolving payment disputes for certain out-of-network services since the launch of the federal IDR portal. From the burdensome open negotiation process to the "large number" of disputes still awaiting payment determinations, the IDR process has been fraught with interruptions, complications, misuse, and confusion. We are hopeful that the changes proposed by the Departments will help address many of these problems. Specifically, we strongly support the new disclosure requirements, centralizing the open negotiations process, increasing flexibility around batching, and promoting equitable access to IDR for low-dollar disputes.

Still, we wish to continue to call attention to the issue of non-payment by insurers after a final payment determination. As we have shared earlier[1], we are greatly concerned that insurers are failing to make timely, legally mandated payment to providers within 30 days following an IDR determination. Unfortunately, recent years have shown that health insurance companies will increasingly flex their market power to impose drastic rate cuts

[1] https://documents.cap.org/documents/cap-letter-IDR-april-2023-2.pdf

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118TH CONGRESS
2D SESSION

S. _____

To amend title XXVII of the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to increase penalties for group health plans and health insurance issuers for practices that violate balance billing requirements, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. MARSHALL (for himself and Mr. BENNET) introduced the following bill; which was read twice and referred to the Committee on

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A BILL

To amend title XXVII of the Public Health Service Act, the Employee Retirement Income Security Act of 1974,

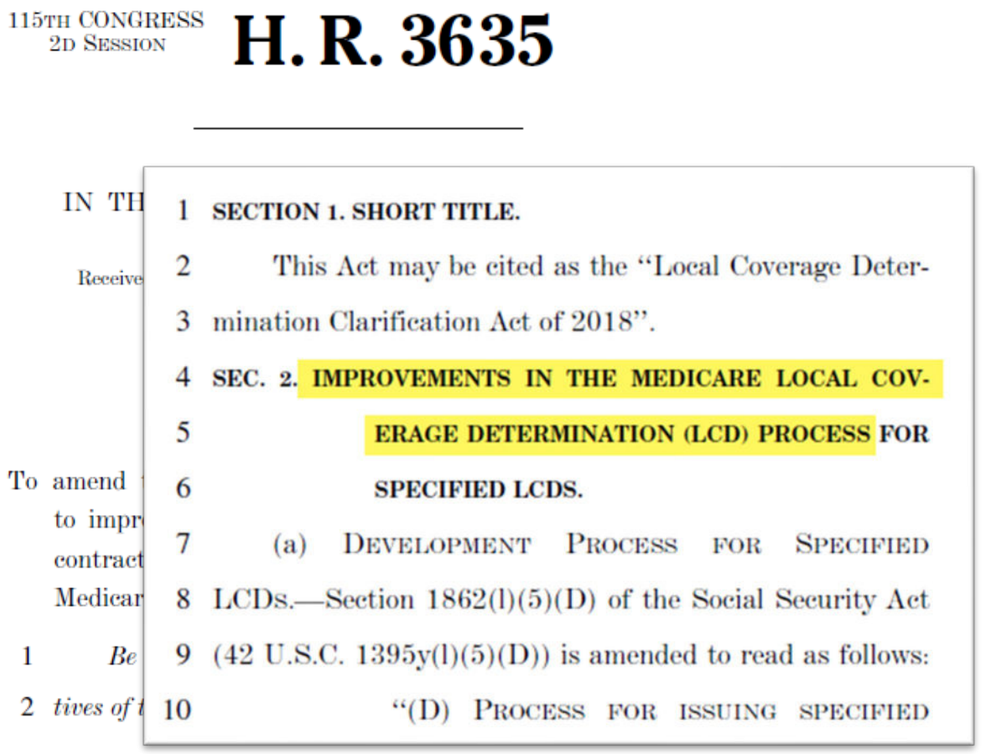
"(D) Paragraphs (1) and (2) of section 9817(a).".

SEC. 3. ADDITIONAL PENALTIES FOR LATE PAYMENT OR NON-PAYMENT AFTER IDR ENTITY PAYMENT DETERMINATION.

(a) PHSA.—

Regulatory and Legislative Coordination

- **Regulations and oversight**
  - **Legislation!**



115TH CONGRESS
2D SESSION

H. R. 3635

IN TH

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SECTION 1. SHORT TITLE.

This Act may be cited as the "Local Coverage Determination Clarification Act of 2018".

SEC. 2. IMPROVEMENTS IN THE MEDICARE LOCAL COVERAGE DETERMINATION (LCD) PROCESS FOR SPECIFIED LCDS.

(a) DEVELOPMENT PROCESS FOR SPECIFIED LCDS.—Section 1862(l)(5)(D) of the Social Security Act (42 U.S.C. 1395y(l)(5)(D)) is amended to read as follows:

"(D) PROCESS FOR ISSUING SPECIFIED

Fact Sheets Oct 03, 2018

Summary of Significant Changes to the Medicare Program Integrity Manual Chapter 13 – Local Coverage Determinations

Coding Coverage

Share

Summary of Significant Changes to the Medicare Program Integrity Manual Chapter 13 – Local Coverage Determinations

The Centers for Medicare & Medicaid Services (CMS) has revised chapter 13 of the Medicare Program Integrity Manual (PIM). This chapter describes the local coverage determinations (LCD) process. The revision was in response to a provision of the 21st Century Cures Act intended to improve transparency in the LCD process. The manual includes instructions, policies and procedures for Medicare Administrative Contractors (MACs) that administer the Medicare program in different regions of the country, as well as guidance for stakeholder engagement in the process. The revised manual includes:

Local/State and Federal Coordination

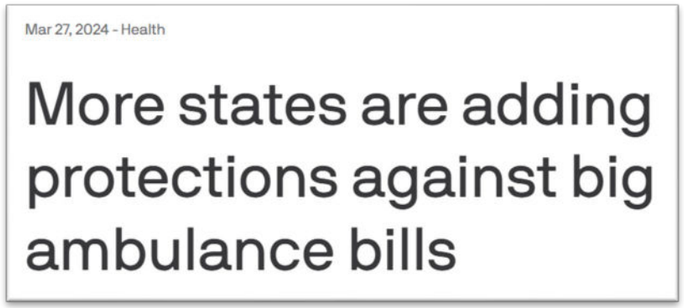
JUL 15, 2015 | MORE ON BILLING AND COLLECTIONS

New York's 'no-surprises' law takes hold to end balance billing

That law, which became effective April 1, significantly expands existing consumer protections.

Surprise Medical Bills Cost Americans Millions. Congress Finally Banned Most of Them.

Efforts to solve the common consumer problem had been stalled by lobbying pressure and legislative squabbles.



State legislators have pursued several strategies to improve hospital price transparency enforcement. Arizona, Indiana and Virginia codified federal price transparency rules into state statute—with the Arizona legislation requiring its health department to annually verify price transparency compliance. Arkansas, Colorado and Texas established state-level penalties for hospitals not in compliance. Colorado also prohibited noncompliant hospitals from engaging in certain debt collection practices for unpaid medical bills.

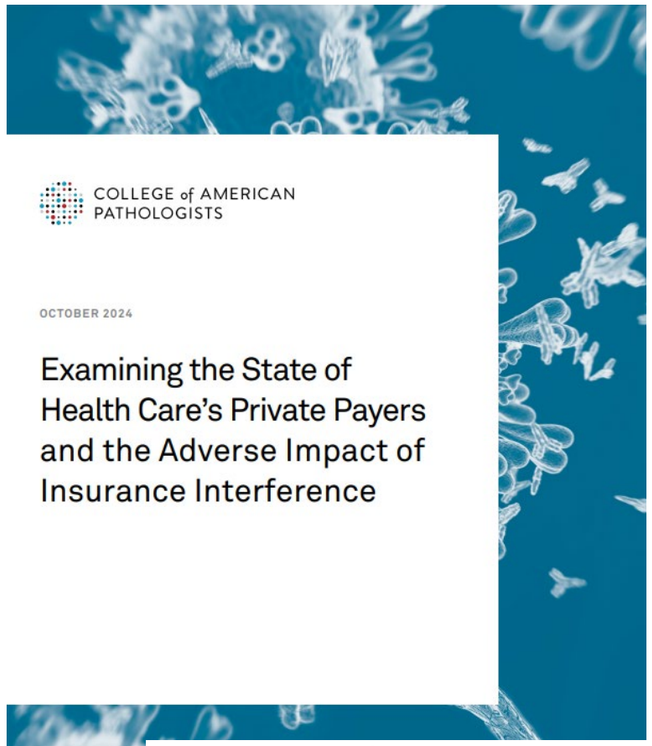
A New Trump Order May Make More Health Care Prices Public

The president calls it 'a giant step towards a heath care system that is really fantastic.' Experts are less sure.

Local/State and Federal Coordination

- State Regulatory Agencies/Departments
- State Boards/Commissions
- State Legislature
- Federal Reps
- Local Media
- State Societies/Associations

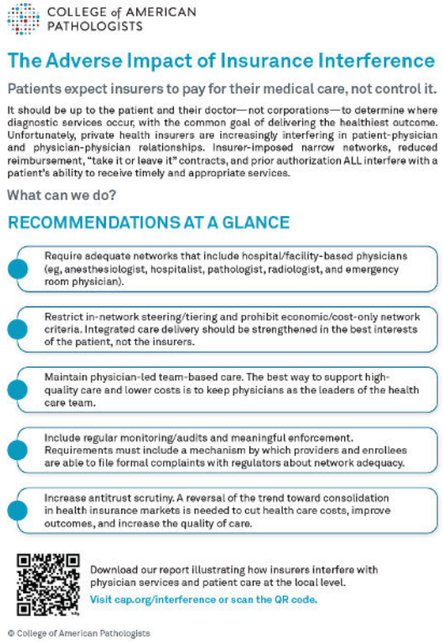
Other Coordination – Communications?



BUSINESS INSIGHTS | POLICY AND REGULATION

Payer consolidation raises red flags for diagnostic testing, pathology leaders

Liz Carey
Oct 23, 2024



The New York Times

OPINION
LETTERS

Maximizing Profits at the Patients' Expense

April 28, 2024

To the Editor:

This is just the latest example of the schemes deployed by insurers to maximize profits by cutting reimbursements to physicians and shifting medically necessary health care costs onto patients.

The College of American Pathologists has also encouraged lawmakers to enact tougher network adequacy standards that mandate that health plans maintain enough physicians under contract in the patient's local area. Such requirements would give insurance companies the right incentives to cover patient services in the interest of keeping its beneficiaries healthy instead of producing healthier bonuses for its own administrators.

Donald Karcher
Washington
The writer is president of the College of American Pathologists.

Other Coordination – Grassroots?

- **Grassroots turns “regulatory” into “relatable”**
  - **Public comment campaigns**
  - **Collect real-world stories, feedback**
  - **Build relationships that last beyond the comment period**

Other Coordination – Compliance?

- **Resources, toolkits, webinars, roundtables…**

Other Coordination – Stakeholders?

- **Leverage industry alliances**

Regulatory Advocacy – Concluding Thoughts

- **Decreased federal workforce + *Loper Bright* = increased need for your expertise and strengthened coordination**
- **Watch for reduced comment opportunities, also increases need for creativity and coordination**

Questions?