

Services

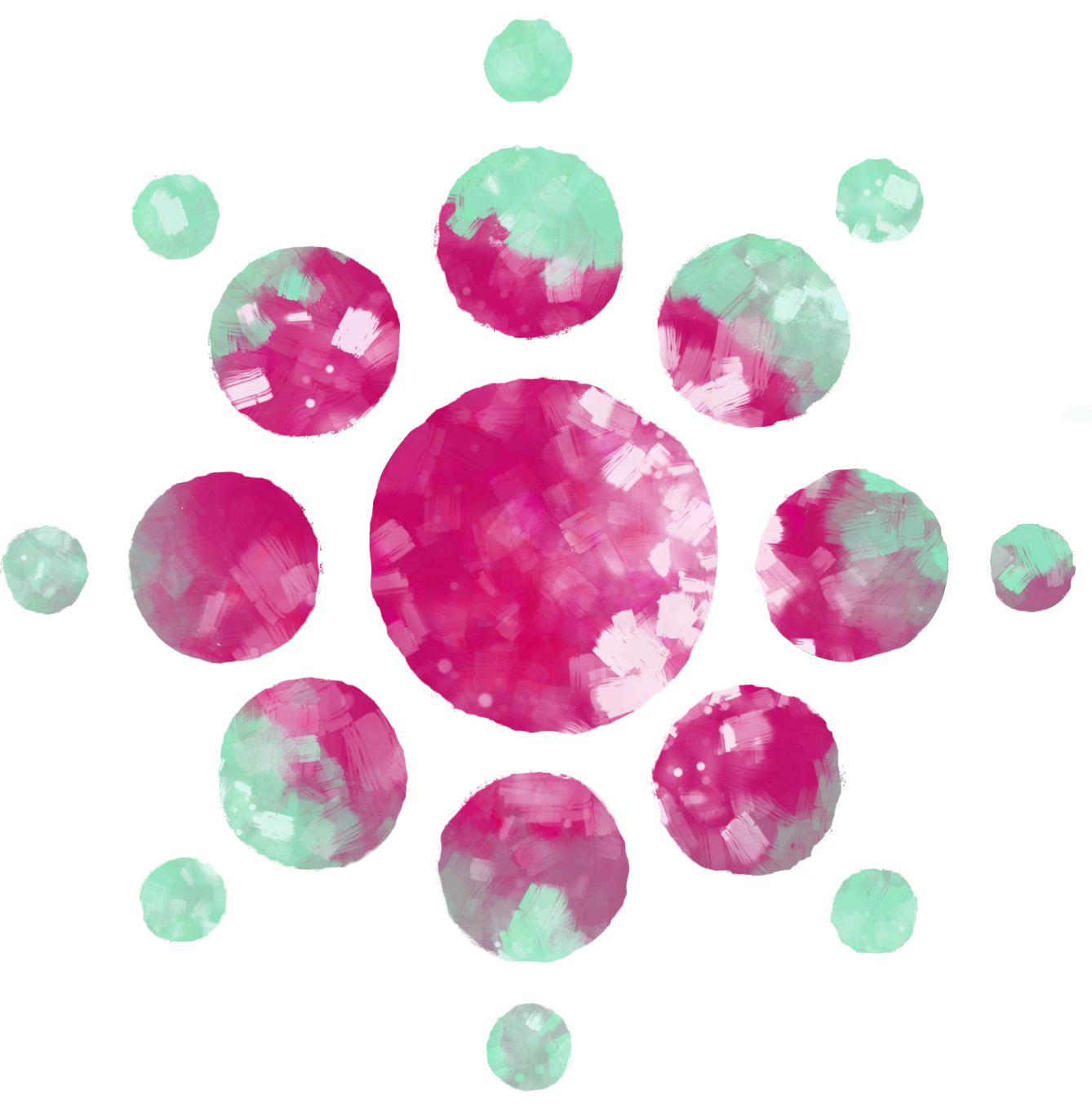
A clinical approach to market access, regulatory, and policy strategies leveraging decades of CMS, FDA, and health system expertise, plus direct patient care.

Market Access: From Seed to Full Commercialization

We share the same goal as our clients and the American public: for the highest-quality care to be adopted, accessible, and covered. To get to market, innovative care solutions need the support of expert teams capable of ensuring all the needs of engaged stakeholders—patients, physicians, health systems, and insurers—are met to allow for appropriate, meaningful adoption of novel products and services.

Our distinguished group of MDs, JDs, MPHs, and MBAs will support your team at every point in the Market Access strategy we'll create together. We are executive-level former regulators, practicing clinicians, lawyers, and patient access experts who have spent our careers dedicated to patients and their care.

Our work specializes in deep knowledge and understanding of commercial and government payers, health system purchasing, quality assessment, and health technology assessment organizations. This allows our team to thoughtfully engage the stakeholders companies will need to navigate as they come to market.



Previous Market Access Work



Regulatory: Meticulous Counsel for Healthcare's Most Complex Issues

Whether you represent a health system or a medical device, drug, technology, or therapeutic company, regulation of the medical industry can be highly technical. With our backgrounds working in leadership positions at CMS and FDA, we are rooted in a wealth of regulatory knowledge.

We are the leading voice to:

- Provide counsel to health systems and their related stakeholders on Medicare payment, immediate jeopardy status, quality assessment, Medicare standing, quality measurement and outcome reporting, litigation support, expert testimony for the purposes of ALJ or litigation proceedings, FDA compliance, and more.
- Advise on regulation of novel technologies including devices, AI, digital therapeutics, pharmaceuticals, and vendor infrastructure.
- Provide education on federal processes and procedures across Federal Agencies.
- Guide best practices in order to gain federal recognition for your product or service.



Previous Regulatory Work



Client: Major Law Firm
Services: Analyze and explain highly technical aspects of the Medicare program and how hospitals, nursing homes, hospice, and laboratories get accredited or lose accreditation, related to Medicare payment.

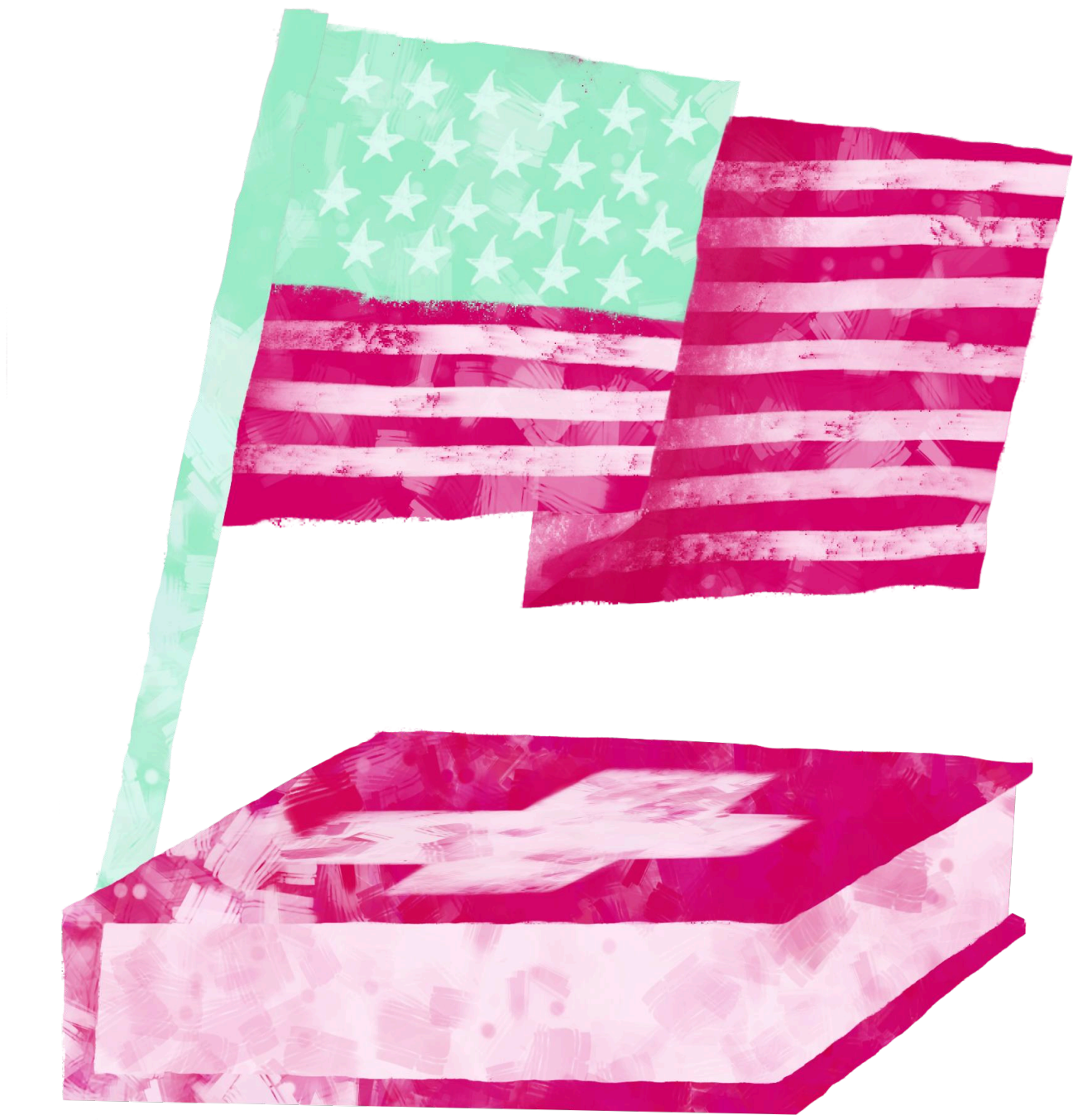
Client: Health System
Services: Counseling on quality assessment and outcome reporting to ensure appropriate compliance with the Medicare program.

Client: Medical Device Company
Services: Give FDA counsel on a wide variety of issues touching product labeling to filing and more.

Policy: Shaping the Healthcare Landscape

Excellent patient care backed by evidence should be fundamentally bipartisan. We approach our policy counsel with a deep bench of clinical, commercial, and regulatory expertise to provide advice that furthers health policy and seeks data-backed reasoning within the complex healthcare landscape.

As an expert, bipartisan counsel, we function like an extension of your team to analyze, draft, and facilitate the dissemination of policy solutions that work for you. This includes responding to RFIs from both Congress and Federal Agencies and assisting in Comment drafting and technical guidance pertaining to regulatory and statutory changes. We do this by partnering with our vast network of connections: patient advocates, physician associations, hospital associations, and other industry leaders.



Previous Policy Work



Client: Healthcare Company
Services: When a client found that their digital health product was no longer interoperable due to policy changes, we worked together to rescope how they told their story and the importance of collecting that data for patient care. We arranged dozens of meetings with healthcare leaders, patient advocates, EHR and technology vendors, and interoperability experts to influence how stakeholders could communicate to the federal government and third parties the importance of their technology and its need for seamless data transmission

Client: Who?
Services: A client used Artificial Intelligence as a tool for improving patient care but did not have a clear pathway for reimbursement due to a lack of clear benefit category under the current scoping of their tool. We helped to rescope what their product was capable of doing and helped develop their CMS engagement strategy to allow for sufficient payment for the product.

Client: Who?
Services: A client had a new diagnostic that could improve the quality of care and patient outcomes. We helped develop a strategy to engage CMS and other key stakeholders to properly incentivize high-quality care, including the use of their technology.

Contact Us

Here is where a valuable partnership begins to grow. Tell us about you.



First Name*

Last Name*

Company*

Email Address*

Phone Number

Preferred Contact Method*

Which service(s) are you interested in?

☒ Market Access

☐ Regulatory

☐ Policy

☐ Other

Message

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