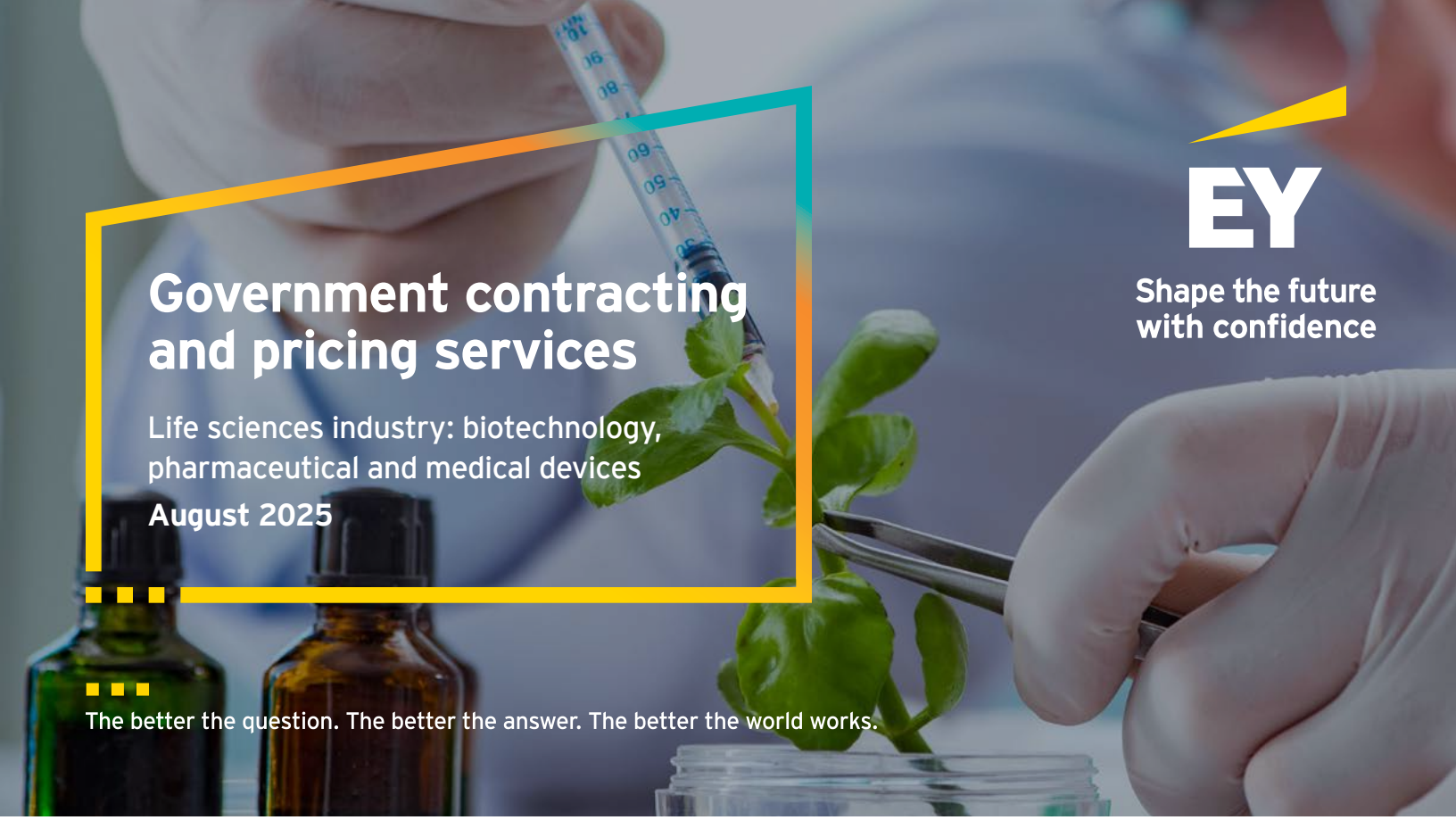

Government contracting and pricing services

Life sciences industry: biotechnology, pharmaceutical and medical devices

August 2025

Shape the future with confidence

The better the question. The better the answer. The better the world works.

Pricing and rebate programs

How we help our clients mitigate compliance risk through knowledge sharing, innovation and industry insights

Medicaid Drug Rebate Program (MDRP) and Public Health Service 340B Drug Pricing Program (340B) compliance

Assist pharmaceutical manufacturers through the regulatory process, including the establishment of compliant policies, procedures and practices for administering the programs; development and assessment of average manufacturer price (AMP) and best price (BP) methodologies; assistance with compliance assessments; and help with voluntary disclosures

Average sales price (ASP) compliance

Assist pharmaceutical manufacturers through the regulatory process, including the establishment of compliant calculation and reporting policies, procedures and practices; development and assessment of ASP methodology pursuant to the Medicare Modernization Act; assistance with compliance assessments; and help with voluntary disclosures

Wholesaler contract compliance assessments

Assist pharmaceutical manufacturers in assessing contract compliance of their wholesalers and distributors, including analytics of chargebacks, returned products (including negative chargebacks), contract membership validation, and inventory to validate product pedigree and manufacturer sourcing

Government program support system assessments

Assist pharmaceutical manufacturers in assessing government program systems, applications and report-writing features to enhance data collection, system output, report generation, record retention and audit trail capabilities, as well as provide system integration support during system updates and new installations

Fee-for-service compliance assessments

Assist pharmaceutical manufacturers in the bona fide and fair-market-value assessments of service fees paid to wholesalers, distributors and other customers

Veterans Affairs (VA) Federal Supply Schedule (FSS) compliance

Assist pharmaceutical manufacturers through the regulatory process, including the establishment of compliant policies, procedures and practices for administering FSS contracts; the FSS contract solicitation process (proposal, pricing strategy and contract negotiation); development and assessment of nonfederal average manufacturer price (NFAMP) methodologies; development of small business subcontract plans; assistance with compliance assessments; and help with voluntary disclosures

Managed care organization (MCO) contract compliance assessment

Assist pharmaceutical manufacturers in assessing MCO contract compliance with services tailored to the unique characteristics of the manufacturer, including rebate validation of 100% of the prescription claims data, competitive co-payment analytics to test formulary compliance and market share formulary management

Independent review organization (IRO) assessments

Acting as the IRO for pharmaceutical manufacturers under the Corporate Integrity Agreements (CIAs), conduct transactions testing, assessment and evaluation of systems, policies, processes and procedures related to government contracting and pricing functions

Our team of professionals is focused on government contracting and price reporting in the life sciences industry, with deep experience in pricing matters related to programs such as Medicaid, Medicare, 340B, the Veterans Health Care Act, TRICARE, VA FSS and individual state price reporting requirements.

About EY Government Contracting and Pricing Services

- We are a national practice group of more than 50 professionals focused exclusively on government contracting and pricing matters.
- We have experience in government agency and the enforcement of pricing, rebate program policy and regulation.
- Experience in assisting our clients during audit or inquiry from:
  - Department of Health and Human Services Office of Inspector General
  - Department of Veterans Affairs Office of Inspector General
  - Department of Justice
  - Various state attorneys general

Our experience as an independent review organization (IRO) spans more than 50 organizations CIAs, including a number of pharmaceutical companies.

Our experience in assisting pharmaceutical, biotech and medical device companies includes helping clients assess and enhance compliance and internal control infrastructures through hands-on advisory support, internal audits and independent diagnostic evaluations.

Sample services we provide to our life sciences industry clients

- Voluntary disclosures
- Policies and procedures
- Trade class studies
- Contract administration
- Customer contract compliance
- Data and document management
- Gross-to-net analysis
- Legislative and regulatory risk
- Intellectual property and royalty recovery assessment
- Internal audit outsourcing and teaming
- Product pricing strategy and modeling
- Sales and marketing compliance
- Supply chain assessment
- Service fee valuation and assessment
- Compliance infrastructure
- Information technology systems assessment and integration
- Independent Review Organization

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EY | Building a better working world

EY is building a better working world by creating new value for clients, people, society and the planet, while building trust in capital markets.

Enabled by data, AI and advanced technology, EY teams help clients shape the future with confidence and develop answers for the most pressing issues of today and tomorrow.

EY teams work across a full spectrum of services in assurance, consulting, tax, strategy and transactions. Fueled by sector insights, a globally connected, multidisciplinary network and diverse ecosystem partners, EY teams can provide services in more than 150 countries and territories.

All in to shape the future with confidence.

About Forensic & Integrity Services
Dealing with complex issues of fraud, regulatory compliance and business disputes can detract from efforts to succeed. Better management of fraud risk and compliance exposure is a critical business priority – no matter the size or industry sector. With approximately 4,500 forensic professionals around the world, we will assemble the right multidisciplinary and culturally aligned team to work with you and your legal advisors. We work to give you the benefit of our broad sector experience, our deep subject-matter knowledge and the latest insights from our work worldwide.

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ED None

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