

Our services

- Identify opportunities to improve business processes and compliance with Medicare, Medicaid, PHS, VA, State Assistance and FSS programs
- Address existing gaps in policies, procedures and controls
- Improve the interface between government price reporting and core transaction systems

How can pharmaceutical and life sciences companies comply with the increasing demands of government price reporting?

Various governmental regulatory and oversight organisations continue to scrutinise pharmaceutical companies' government price reporting practices. Government investigations have led to negotiations and settlements with the Office of the Inspector General (OIG), requiring several pharmaceutical manufacturers to comply with the terms and conditions of a Corporate Integrity Agreement (CIA). CIAs, which can last from five to eight years, are costly, consume internal resources and are challenging to implement.

The Deficit Reduction Act of 2005 (DRA) and Final Rule, published July 2007, poses new challenges to the pharmaceutical manufacturer as both updated the Medicaid rules around reporting frequency, calculation methodologies, treatment of authorised generics and other obligations. In addition to the ASP requirement, the Final Rule includes certifying the accuracy of the AMP and BP calculations by the manufacturer's CEO, CFO, or an individual who reports directly to them and who has delegated authority to sign on their behalf. In addition, the calculation of Average Sales Price (ASP) through the enactment of the Medicare Prescription Drug, Improvement, and Modernisation Act of 2003 (MMA), coupled with the increased scrutiny placed on reporting to comply with Sarbanes-Oxley has brought a heightened level of attention to this area. These circumstances have forced pharmaceutical manufacturers to examine the policies, procedures and controls associated with government price reporting and the core transaction system used to calculate these reportable amounts. Companies need to assess whether discrepancies exist between policy and practice and between regulatory and legislative guidance and develop steps to remediate gaps.

How can PwC help your organisation?

PwC provides comprehensive government price reporting compliance services that assess the policies, procedures and systems which support the submission of pricing information to federal and state agencies. We understand the complexity surrounding the pharmaceutical industry's underlying sales and marketing information systems, promotional and discounting programmes, and the issues that rise when applying them to complex and at times, unclear government reporting requirements. PwC brings the following experience to the table:

- We have reviewed policies, procedures, systems and controls that support government price-reporting and claims-processing requirements. We have helped clients develop new policies and implement process improvements identified during our review. Additionally, we have assess government price reporting calculations, focusing on the calculation methodologies for:
 - Medicare ASP
 - Medicaid Average Manufacturer Price (AMP) and Best Price (BP)
 - Public Health Service (PHS) pricing
 - Federal Supply Schedule (FSS), Non-federal Average Manufacturer Price (Non-FAMP) and Federal Ceiling Price (FCP)
 - Various other government agency price-reporting requirements

Contacts

Tony Farino

Partner
anthony.l.farino@us.pwc.com
+1 312 298 6841

Douglas S. Strang

Partner
douglas.s.strang@us.pwc.com
+1 267 330 3045

Peter Claude

Partner
peter.claude@us.pwc.com
+1 415 606 2781

Jonathon L. Kellerman

Principal
jonathon.l.kellerman@us.pwc.com
+1 267 330 2466

- Working with senior management, internal and external counsel, and the government, we have assisted pharmaceutical manufacturers negotiate and implement CIAs and develop the Independent Review Organisation (IRO) workplan. In fact, PwC serves as the IRO for many CIAs currently in place within the pharmaceutical industry. This distinction attests to our extensive skill in developing and executing efficient and effective procedures to test compliance.
- We have significant experience helping companies respond to US Department of Justice inquiries, evaluating concerns regarding historical government pricing practices and preparing refilings with the Centers for Medicare and Medicaid Services (CMS), the Veterans Administration (VA) or others. Related PwC services include:
 - Leveraging technology to efficiently identify and retrieve finance, sales and accounting information necessary for government pricing calculations
 - Calculations government pricing, including Medicaid rebate (ie, AMP/BP), Medicare ASP, PHS, FSS and VA pricing
 - Analysing potential financial exposure related to previously reported government pricing
 - Helping corporate management assess ASP calculation accuracy before management's quarterly certification and filing with CMS

www.pwc.com/pharma

This publication has been prepared for general guidance on matters of interest only, and does not constitute professional advice. You should not act upon the information contained in this publication without obtaining specific professional advice. No representation or warranty (express or implied) is given as to the accuracy or completeness of the information contained in this publication, and, to the extent permitted by law, PricewaterhouseCoopers does not accept or assume any liability, responsibility or duty of care for any consequences of you or anyone else acting, or refraining to act, in reliance on the information contained in this publication or for any decision based on it.

© 2011 PwC. All rights reserved.
Not for further distribution without the permission of PwC. "PwC" refers to the network of member firms of PricewaterhouseCoopers International Limited (PwCIL), or, as the context requires, individual member firms of the PwC network. Each member firm is a separate legal entity and does not act as agent of PwCIL or any other member firm. PwCIL does not provide any services to clients. PwCIL is not responsible or liable for the acts or omissions of any of its member firms nor can it control the exercise of their professional judgment or bind them in any way. No member firm is responsible or liable for the acts or omissions of any other member firm nor can it control the exercise of another member firm's professional judgment or bind another member firm or PwCIL in any way.

Global Pharmaceutical and Life Sciences Industry Group

The Global Pharmaceutical and Life Sciences Industry Group at PwC is dedicated to delivering effective solutions to the complex business challenges facing pharmaceutical and life sciences companies. A global leader in serving the pharmaceutical and life sciences industry PwC has extensive experience working with companies on industry-specific strategic, operational, and financial issues. Our expertise includes assurance, tax and advisory services, as well as specialised capabilities in regulatory compliance, risk management, performance improvement and transaction support. In helping our clients, we draw on the full knowledge and skills of PwC's professionals. More than 161,000 people in 154 countries connect their thinking, experience and solutions to build public trust and enhance value for clients and their stakeholders.