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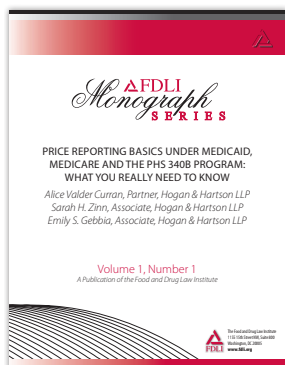
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Volume 1, Number 1

Price Reporting Basics under Medicaid, Medicare and the PHS 340B Program: Planning for Both Compliance and Commercial Success

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Every drug manufacturer that seeks to have its products paid for by the Medicaid or Medicare Part B programs must report commercial price points to the federal government on a monthly and quarterly basis, and certify that pricing data. Those pricing data determine the discount amount that the manufacturer must provide each State Medicaid program on the manufacturer's products, the reimbursement rate for the manufacturer's products under Medicare Part B, and the upper limit on the price that the manufacturer can charge to certain federal grantees and safety net providers. These price calculations are the subject of complex regulatory requirements and have been the basis for several federal and state enforcement actions resulting in settlements in the hundreds of millions of dollars. This monograph will provide

an overview of the legal requirements that govern these calculations, practical guidance regarding how the calculations actually work, insight into the common issues that arise and require monitoring, and sample documents to use as a starting point for documenting calculation methodology.

After reading this monograph, you'll be better able to:

- 1) Understand the calculation mechanics for these price points;
- 2) Spot the price reporting issues arising in common commercial arrangements; and
- 3) Prepare compliance documentation regarding these price reporting obligations.

Volume 1, Number 2

GRAS ROOTS: How to Advocate for and Defend "General Recognition" of Safety for Food Ingredients and Drugs

James T. O'Reilly, Professor, University of Cincinnati College of Law; Counsel, Baker & Daniels

The FDA term "Generally Recognized as Safe" (GRAS) means a product that enjoys an important exception from costly testing. The product that is "GRAS" need not spend millions to pass premarket approval testing. From its roots within 1938 and 1958 legislation, GRAS status has grown to be a very critical part of the nation's food and drug systems. An additive can be GRAS through scientific procedures, including general agreement in the scientific community about the safety of the additive. For additives that have been used for many years, general recognition of safety can be achieved through experience based on common use in foods. This requires a substantial history of consumption for food use by a significant number of consumers.

After reading this monograph, you will be better able to:

- 1) Defend a product's GRAS status at FDA;
- 2) Advise clients about GRAS coverage for their products; and
- 3) Determine how FDA is likely to view your client's claims about General Recognition.



Volume 1, Number 3

Reviewing Clinical Trials and Observational Studies: A Practical Guide to Assessing Scientific Validity and Causal Leverage

Lance L. Shea, *Partner, Fulbright & Jaworski L.L.P.*

Greg A. Burkhart, *Former FDA Team Leader*

Investigators, manufacturers and regulators increasingly face a vexing issue—what body of evidence constitutes proof that medical products are safe and effective under the proposed conditions of use. This monograph reviews the scientific concepts and principles necessary to weigh the strength of evidence on safety or efficacy derived from clinical trials and epidemiological studies. The review is presented using standard lay terminology to allow the reader to gain a real-world understanding of the concepts that underlie the legal basis for regulatory decisions on medical product approval or post-marketing changes to the conditions of use.

After reading this monograph, you will be better able to:

- 1) Identify major types of studies used to assess efficacy or safety;
- 2) Assess in general terms the strength of study results based on study design features and interpretation methods; and
- 3) Better appreciate a body of empirical literature that develops for marketed drugs and medical devices.

Volume 1, Number 4

International Prescription Product Recalls: A Practical Guide

James M. Wood, *Partner, Reed Smith LLP, San Francisco*

Areta L. Kupchyk, *Partner, Reed Smith LLP, Washington, DC*

This monograph analyzes the basic obligations of a recall of a prescription product in the United States and how these obligations might be affected by different obligations in other countries. The monograph demonstrates the need for and implementation of a global recall team as well as the many resources that need to be in place for an effective recall policy. FDA's drug recall authority evolved through a rather convoluted path, with no specific authority to order a company to recall a drug. FDA can seize an adulterated drug and prosecute those responsible. It can also require reports about recalls and prescribe mandatory procedures that facilitate recalls.

After reading this monograph, you'll be better able to:

- 1) Understand the global implications of prescription product recall;
- 2) Understand the varying recall requirements of countries outside the United States; and
- 3) Understand the importance of forming a world-class global recall team.

Volume 1, Number 5

Selling Pharmaceuticals to the Federal Government: Federal Supply Schedule Contracting and Federal Ceiling Price Requirements

Joy Sturm, *Partner, Hogan & Hartson LLP*

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For a drug manufacturer to have its products paid for by Medicaid, Medicare Part B, or by the "Big 4" Federal agencies, it must enter into a Federal Supply Schedule (FSS) contract with the Department of Veterans Affairs (VA) and agree to charge prices to the Big 4 that do not exceed calculated "Federal Ceiling Prices." Federal Ceiling Prices are computed using commercial price points that manufacturers are required to calculate and report to the Federal government on a quarterly and annual basis, in accordance with the Veterans Health Care Act of 1992 and voluminous guidance issued by the VA. In addition to these statutory price reporting requirements and price caps, manufacturers are subject to numerous pricing and disclosure requirements under standard FSS contract terms. This monograph provides insight into the calculations and reporting requirements; best practices for compliance with FSS pricing and disclosure requirements; and sample documents used for formulating calculation methodologies and in preparing FSS contract documentation.

After reading this monograph, you will be better able to:

- 1) Understand the Federal Ceiling Price and the Non-Federal Average Manufacturer Price calculation requirements;
- 2) Understand the pricing and disclosure requirements of the VA FSS contracts for pharmaceuticals; and
- 3) Understand the interplay between the pricing and reporting requirements of the FSS contract and the Veterans Health Care Act of 1992.

Volume 1, Number 6

Opportunities and Challenges to Consider With the 505(b)(2) New Drug Application Regulatory Pathway

Alan Minsk, *Partner, Arnall Golden Gregory LLP*

The 505(b)(2) NDA regulatory pathway is a popular pathway for pharmaceutical companies (and the investors who support them) to obtain marketing authorization in the United States. Some companies lack the resources to develop and bring to market new chemical entities, while others do not want to market generic products. But for other firms, the 505(b)(2) NDA hybrid approach provides a valuable opportunity to obtain FDA approval in what might result in a more truncated manner while also taking advantage of marketing benefits. Although the provision has been in existence for 25 years and FDA has issued substantial guidance on the subject, the pathway is not always clear and definitely not a good option for everyone. This monograph will describe the opportunities and challenges to consider when exploring the 505(b)(2) NDA option.

After reading this monograph, you will be better able to:

- 1) Determine whether the 505(b)(2) approach is right for you or your client;
- 2) Analyze the advantages and potential obstacles of using 505(b)(2); and
- 3) Maximize the benefit, if you choose to utilize the 505(b)(2) approach.

Want to Be a Monograph Author? Got a Great Idea for a Monograph?

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