

Case Study
Rule Monitoring in the US
Pharmaceutical Sector



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Rule Monitoring in the US Pharmaceutical Sector



About the Client



- The client is the government contract pricing team of a large pharmaceutical company

Client Objectives / Goals



- Monitor proposed rule/ final rule/ agency guidance related to specific government programmes focused on drug pricing
- The regulations covered include:
 - Medicare Part D
 - Medicaid
 - PHS/340B
 - DoD/TRICARE
 - VA
 - Health Exchanges
 - Medicare Part B

Approach and Methodology



- Conducted preliminary research during the first week after each quarter to identify amendments made to the select regulations
- After the final check (to identify additional amendments), a summary level slide showing the spread of amendments across different stages of the process flow was prepared
- Captured the following information for each amendment:
 - Summary of the changes (programme changes, price reporting/ calculation changes, AMP changes, call letters, etc.)
 - Impact areas (changes to Safe Harbour Requirements, affect on usage of coupons/ vouchers, enrolment changes, etc.)
 - Important dates (due date for comments, date for implementation)

Sample Output



Results / Value-add



The contract pricing team was able to stay abreast of all the regulatory changes and requirements, and was able to **respond accordingly and in a timely manner**