Covered Entity 360

Global Drug Manufacturer | **Life Sciences** | **Compliance**

Background & objectives

This global life sciences company operates with a broad network comprising over 250 subsidiary companies across 60 countries. As part of its initiatives to streamline operations, the company has sought to enhance its governance and operational processes using advanced technologies like AI, specifically targeting the inefficiencies in managing inquiries under the 340B Covered Entity program. The 340B Covered Entity system we implemented, named Covered Entity 360, offers significant benefits to the life sciences sector, specifically pharmaceutical companies and drug manufacturers, by addressing current inefficiencies. This centralized platform transforms the 340B process by replacing spreadsheets, SharePoint documents, and shared group email inboxes with automated workflows. It provides users with a comprehensive 360-degree view, enhancing consistency while building a historical record that is vital for informed strategic decision-making.

Client challenges

Currently, the handling of Covered Entity (340B) inquiries is fragmented and cumbersome, primarily owing to its reliance on manual tracking through tools such as shared Outlook mailboxes and Excel spreadsheets. This mode of operation incurs several challenges:

- **Visibility Gaps:** Stakeholders often lack comprehensive oversight of the inquiry process, leading to coordination issues.
- **Inconsistent Responses in Highly Regulated Area:** Due to manual tracking, stakeholders provide varying responses, which risks non-compliance.
- **Operational Delays**: These inefficiencies have led to delayed processing times, impacting overall productivity and compliance.

KPMG Response

Scope and approach

Scope: KPMG has assisted this life sciences company in revolutionizing the 340B inquiries process by leveraging AI-driven solutions that enhance oversight and operational efficiency.

Approach: Our approach involves integrating AI to streamline email ingestion and automate request management, creating a centralized portal for logging and tracking entity submissions. This dynamic case management system allows users to navigate a comprehensive dashboard that includes unassigned and in-progress cases, along with insightful reports and metrics.

Solution highlights

- **Portal Integration:** Offers a centralized interface for managing requests, including ad-hoc capabilities for urgent inquiries.
- **Log & Track Features:** Users can log entity submissions, track case progress, and review detailed records for comprehensive case management.
- **Request Handling:** Supports diverse request types, while enabling case reassignment, comment addition, and document uploads for greater flexibility.
- **Entity Record Visibility:** Users can view cases related to specific entities, providing insights into contract pharmacy history and communication trails.
- **Routing and Review Processes:** Approval workflows are streamlined by allowing users to send emails and route cases for peer review efficiently.
- **Milestones Tracking:** The progress of cases is tracked through defined milestones, including HRSA terminations and financial data visibility.
- **Reports/Metrics Overview:** Detailed analytics are provided on submission volumes, case closure rates, and $ metrics. Tracks average aging days open per milestone, supporting operational assessments and improvements.

Integrations/ AI Capabilities

- Email Ingestion and Data Extraction
- AI-Based Inquiry Classification
- Self-Serve Analytics with Appian Co-Pilot Features:

Outcomes

- **Market Differentiator:** With a unique proposition and no known competitor solutions in the current market, this offering positions KPMG as a premier partner for digital transformation journeys within the life sciences, capitalizing on industry expertise and strategic alliances.
- **Centralization**: Consolidates inquiry-related data for improved visibility and reduced errors.
- **Automation**: Ensures consistent and efficient processing of inquiries, minimizing compliance risks.
- **Security:** Provides robust data management with role-based access and audit trails.
- **Collaboration**: Coordination is enhanced across teams such as legal, finance, and operations.
- **Analytics:** Tools for strategic planning and decision-making are offered through insightful reporting.
- **Strategic Impact: The solution b**uilds organizational capability to adapt to evolving 340B regulations, ensuring long-term compliance and strategic oversight.

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