

GET TO KNOW THE BDO CENTER FOR HEALTHCARE EXCELLENCE & INNOVATION

# AN INTRODUCTION TO 340B AUDITS

# The BDO Center for Healthcare Excellence & Innovation

The BDO Center for Healthcare Excellence & Innovation brings together the best minds from different disciplines to think in new ways about how to address challenges and seize opportunities in healthcare. Our goal is to deliver fresh insights to our clients and help them implement change.

In today's competitive healthcare environment, it takes sound structure, exceptional talent, and ample support to deliver high performance. BDO understands the healthcare industry and is skillfully positioned to help our clients thrive and prosper in challenging times. Our professionals have applied their in-depth knowledge and experience to organizations across the continuum of the healthcare delivery horizon.

Today's dynamic healthcare environment—marked by intensifying demands from government, the private sector, and consumers—is compelling industry professionals and institutions to develop new ways of doing business, when the definition of “business as usual” changes every day.

We leverage insight and experience across all facets of the healthcare industry to help organizations anticipate change and overcome the many hurdles associated with risk-based reimbursement, policy change, and clinical outcomes. We help our clients find new opportunities to improve performance in the short-term as well as achieve longer-term transformational change.

Our practice brings together healthcare leaders with deep healthcare experience across financial, clinical, operational, data analytics, and legal disciplines. BDO is committed to a uniquely collaborative culture that breaks down barriers, building bridges between the many disciplines required to create robust organizational change, creating seats at the table for all invested parties.

## **The BDO Center for Healthcare Excellence & Innovation works with:**

- ▶ Hospitals & Health Systems
- ▶ Law Firms
- ▶ Payers
- ▶ Physician & Other Provider Groups
- ▶ Private Equity & REITs
- ▶ Social Health Services
- ▶ Long-Term Care

## **We work closely with our clients, matching our resources to the complex and unique needs of each. Our seasoned professionals include:**

- ▶ Healthcare Executives
- ▶ Clinical Practitioners
- ▶ Financial Analysts
- ▶ Economists
- ▶ Statisticians
- ▶ Investment Bankers
- ▶ Forensic Technologists
- ▶ Tax Accountants
- ▶ Auditors
- ▶ Regulatory Specialists

*“Since working with BDO, we have implemented several key new strategies and their role as a business advisor and partner has been invaluable... we are continually impressed by the level of responsiveness and industry knowledge of the entire BDO team. We look forward to many more years of our relationship with BDO.”*

**RHONDA RATCLIFF**  
Life Care Centers of America, Inc.



# Healthcare Industry Experience



# Client success stories

## 340B audit case studies

While we are leaders in connection with numerous healthcare compliance engagements, these three case studies were determined to be most relevant to the services that BDO would provide to you.

### SAFETY NET HOSPITAL



A large safety net hospital system was looking to implement a 340B software and was looking to understand the program requirements to confirm the system was designed accordingly.

- ▶ BDO was able to quickly help the organization map out the program requirements and recommend system controls based on system processes.
- ▶ BDO assisted with pre and post implementation testing to confirm the system was operating as designed and the 340B program compliance program had effective monitoring procedures.

### CONTRACT PHARMACY



A large Northeast hospital system had multiple contract pharmacies and was looking to confirm compliance with 340B program requirements.

- ▶ BDO was engaged to assist management with understanding current operating procedures at the contract pharmacy with a focus on procurement, billing and inventory procedures.
- ▶ BDO identified duplicate discounts and developed recommendations.
- ▶ We performed routine check-ins to confirm recommendations were implemented and confirm issues were remediated.

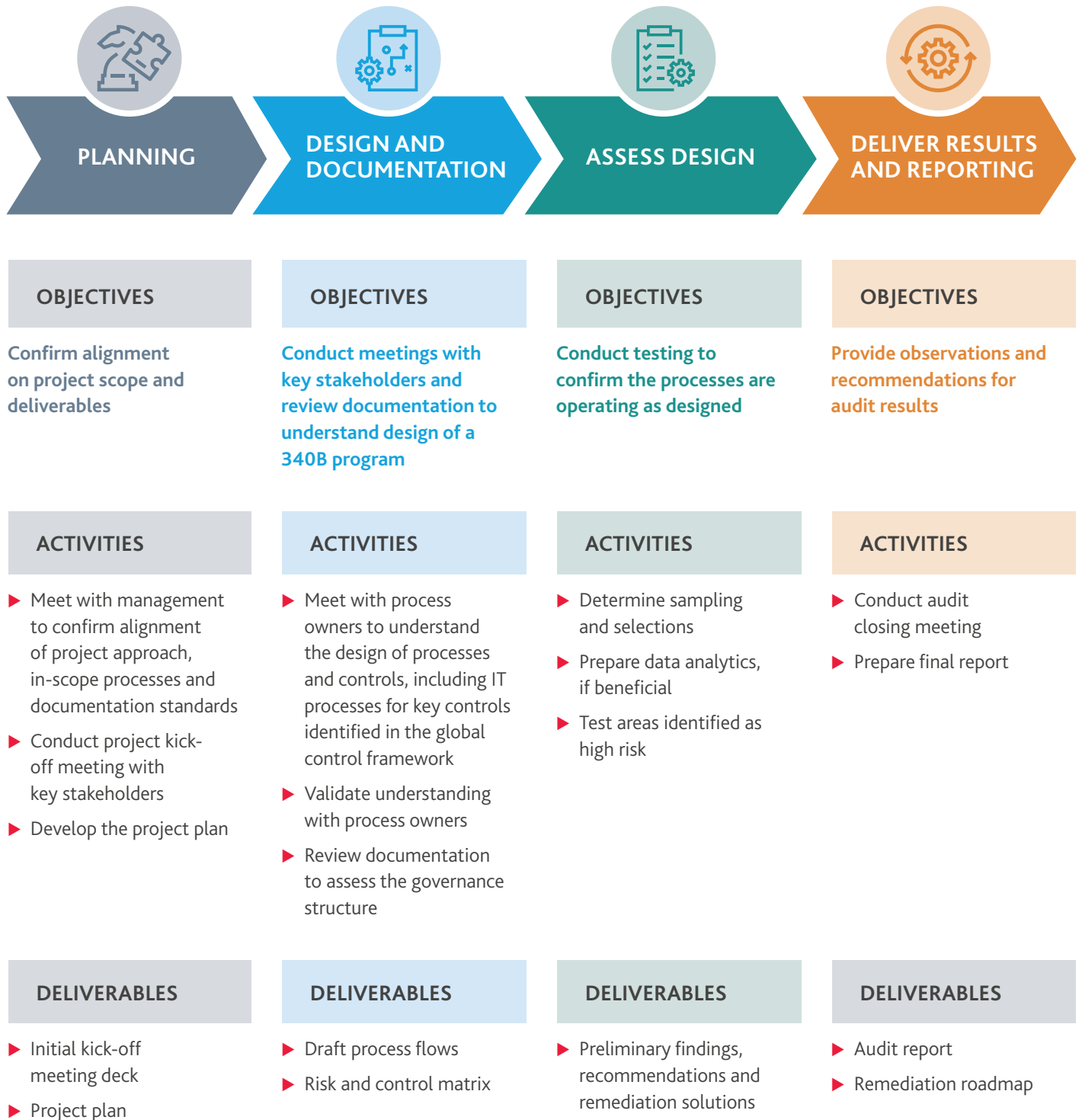
### ACADEMIC MEDICAL CENTER



An Academic Medical Center was looking to confirm compliance with 340B program requirements in preparation for an upcoming HRSA audit.

- ▶ BDO's integrated team assessed scope areas such as diversion prevention procedures, controls to prevent duplicate discounts, purchasing procedures, vendor set up processes and inventory management.
- ▶ BDO collaborated with management to identify control gaps across all scope areas and developed remediation plans that were appropriate based on the organization.

# Overall Approach and Methodology



# 340B Audit Focus Areas

Key focus areas for a 340B audit are summarized below. Prior to executing an engagement, BDO will work with the organization to prioritize high risk areas to scope the engagement.

## GOVERNANCE

- ▶ Review policies and procedures
- ▶ Roles and responsibilities for 340B staff
- ▶ 340B compliance, monitoring and reporting procedures

## DUPLICATE DISCOUNTS

- ▶ Entity's Medicaid billing practices align with its information listed on Office of Pharmacy Affairs website
- ▶ Transaction sample testing
- ▶ State Medicaid regulations
- ▶ Medicaid exclusion file

## PURCHASING

- ▶ GPO prohibition: purchases exclusively on the GPO account
- ▶ Consignment inventory
- ▶ 340B account pricing load
- ▶ Manual invoice uploading process

## INVENTORY

- ▶ Process used to determine inpatient vs. outpatient status
- ▶ Tracking of 340B vs. non-340B drugs
- ▶ Accurate data capture
- ▶ Negative and large positive accumulations
- ▶ Reversals







## Technology and Data Analytics for 340B Audit

Management's expectation of a 340B Audit is to understand where the function is needed most and to deliver timely and relevant audit results.

There are several technologies that BDO auditors utilize to improve the speed and efficiency throughout the audit process.

### **BDO'S VISUALIZATION TOOLS**

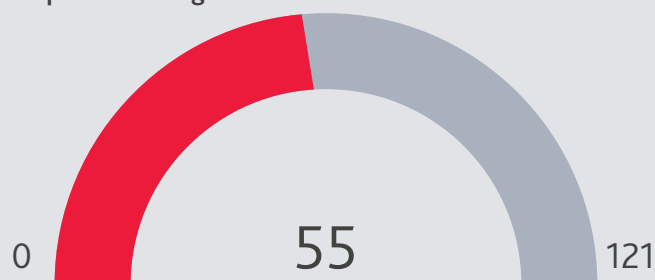
The key to reporting is the ability to tell a story with your data. BDO helps to bring insights and clarity to your information with tools like PowerBI™. Much like the dashboard in a car, a PowerBI™ report displays a selected group of visuals that provides quick insight into the data or the story we are presenting.

## Year-End Testing Status as of January 31, 2020

Control Frequency: ALL Entity: ALL

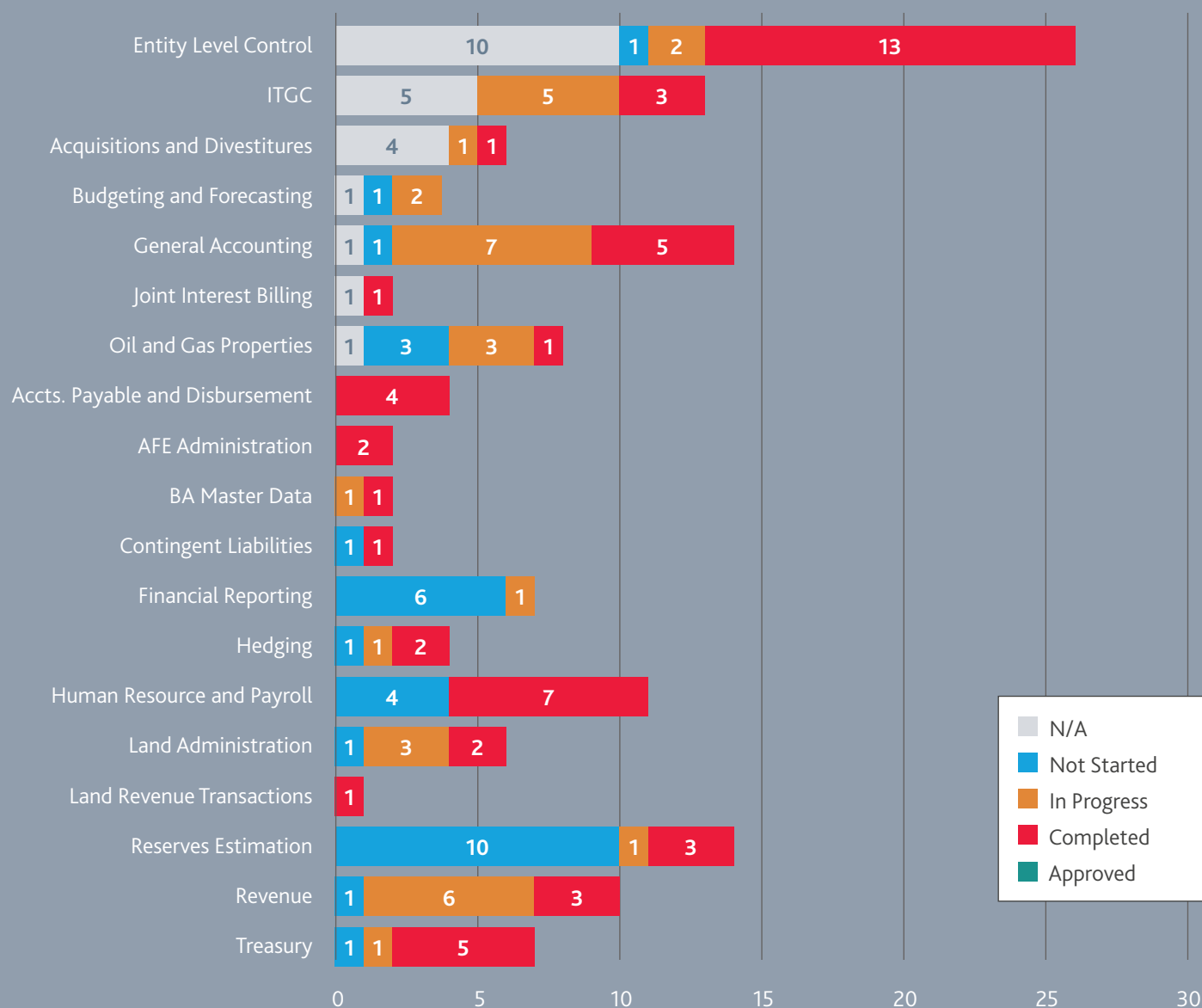
**45.45%**

Completed Testing



### Year-End PBC Status

Process	Not Received		Partially Received		Total
	7	33	9	95	144
<b>Total</b>	7	33	9	95	144







## AUDIT SOFTWARE MANAGEMENT

BDO operates its internal audits within the Pentana Audit management platform. Built by Ideagen, Pentana is a best-of-breed audit automation application that offers a complete solution to risk-based auditing and compliance. The software is designed to drive productivity, manage risk and deliver high quality management information. Pentana Audit allows your organization to implement a consistent methodology compliant with risk and auditing standards. Pentana integrates all aspects of the audit cycle from annual planning to detailed risk assessment and controls testing, through to action tracking and Audit Committee reporting.

## BDO'S COMMITMENTS & ADVANCEMENTS TO DATA ANALYTICS SERVICES

Over the years, BDO has been building a culture of innovation—upping its game when it comes to new technologies.

BDO Advantage includes analytical tools that create data visualizations that enhance our understanding of our clients' information to more dynamically explore and focus our efforts on patterns, trends, and outliers.

We evaluate and analyze data comprehensively and cost-effectively, regardless of format, database platform, or system. Whether assessing millions of records domestically or culling through terabytes of transactions, our professionals provide the insight necessary.



# Our Professionals



## MANDY CARROLL, CFE

Managing Director  
Risk Advisory Services, Engagement Leader  
617-239-7022 / mcarroll@bdo.com

As a Managing Director in BDO's Risk Advisory Services practice, Mandy is an experienced risk executive with a proven track record advising clients on governance, risk control issues with a deep technical knowledge in internal audit services, risk assessment and mitigation, and control monitoring and redesign. With over 10 years of combined risk advisory, internal audit, regulatory compliance and internal controls experience, Mandy provides expertise in enterprise risk assessments, process and controls assessments (including SOX compliance), Pre-IPO control design, internal audit co-sourcing, and performance optimization to identify and creatively solve various business issues.

Mandy is effective at managing and training multidisciplinary teams to arrive at data-driven, fact-based results within time and budgetary constraints. In addition to her continuous focus on exceptional client service, Mandy is committed to diversity and inclusiveness with a focus on developing, empowering and connecting young women professionals and working moms. Additionally, Mandy serves as a mentor for the POSSE program.

### PROFESSIONAL AFFILIATIONS

Certified Fraud Examiner

### EDUCATION

M.B.A in Finance, Suffolk University  
B.B.A. Siena College



## CORTNEY MARCIN

Managing Director  
Healthcare Advisory Services  
212-885-8242 / cmarcin@bdo.com

Cortney Marcin is a managing director in the New York-based BDO's Center For Healthcare Excellence and Innovation with more than 15 years of experience overseeing large scale and complex engagements, both nationally and internationally, for state and local government health and human services agencies, academic medical centers, large healthcare systems, physician practices, investment firms, life sciences companies and law firms.

She has proven experience in guiding organizations to develop and implement sustainable strategies to improve operations, establish internal controls, reduce costs, improve revenues and align strategy to mission. Cortney has developed deep expertise in enhancing reimbursement and financial performance, improving operations, and sustaining change through implementing measurement systems and tools.

Further Cortney has assisted clients in the formation of clinically integrated provider networks aimed at transforming healthcare delivery and implementing value based payment models.

Prior to joining BDO, she worked for a large hospital association where her work focused on advocacy as well as implementing purchasing and reimbursement strategies on behalf of its members. She previously worked with federal, state and local governments across the United States in various capacities around the provision of healthcare and social services.

### PROFESSIONAL AFFILIATIONS

American College of Healthcare Executives

### EDUCATION

M.P.A., Health Care Administration, Syracuse University  
B.A., Political Science, Syracuse University



## PATRICK PILCH, CPA, MBA

Senior Managing Director  
National Healthcare Advisory Practice Leader & Co-Founder  
212-885-8006 / ppilch@bdo.com

Patrick leads the firm's Healthcare Advisory practice with more than 30 years of healthcare, financial services, operational management and restructuring experience. Leading The BDO Center for Healthcare Excellence & Innovation, Patrick works with BDO's team of accomplished clinical and business advisory professionals to help healthcare organizations thrive in this era of daunting challenge and boundless opportunity. He is experienced in delivering transformative services that help healthcare organizations comprehensively redefine operations and processes to respond to patient-centric demands.

Patrick has significant experience providing strategy, business transformation, interim management, mergers and acquisitions advisory, restructuring, turnaround, and performance improvement services to organizations and their stakeholders. Advising nonprofit, for-profit and public healthcare organizations, he conducts operational and financial assessments, develops future state models and roadmaps, and implements alignment strategies across the continuum of care to improve quality and delivery. Patrick has served as a strategic advisor to hospitals, boards, foundations and healthcare systems in matters involving mergers, acquisitions, divestitures, real estate holdings, and other assets and restructurings.

### PROFESSIONAL AFFILIATIONS

American Institute of Certified Public Accountants  
Connecticut Society of Certified Public Accountants  
Healthcare Financial Management Association  
Turnaround Management Association  
Columbia Business School Healthcare and Pharmaceutical Management Program Advisory Board Member  
FINRA, Investment Banking Representative (Series 79)  
Certified Public Accountant

### EDUCATION

M.B.A., Columbia School of Business  
B.S., Accounting, Fairfield University



## SAL RENZO, CPA, MBA

Managing Director  
Health Care Advisory Services  
212-798-4022 / srenzo@bdo.com

Sal is a managing director and has more than 20 years of experience in healthcare, financial services, operational leadership, and restructuring. He has worked with numerous healthcare organizations, including hospitals and health systems, physician groups, long term care organizations, behavioral health organizations, dialysis providers, payers and specialty pharmacies. He has provided guidance on the financial impact of regulatory changes on service lines and programs, and served in interim management leadership roles for healthcare organizations during corporate reorganizations and financial restructurings. He has a varied range of experience in mergers & acquisitions and private placements advisory and has assisted healthcare clients, including biotechnology, medical device, and pharmaceutical clients raise capital for acquisitions and growth initiatives.

He has served in interim management roles both operations and finance for healthcare organizations during corporate reorganizations and financial restructurings. He has advised on strategic initiatives, provided guidance on the financial impact of regulatory changes on service lines and programs, and also has experience assisting corporate compliance and internal audit departments with co-sourced engagements.

He has strong experience in project management and leading multidisciplinary teams to drive performance improvements and cost reductions in hospitals and other healthcare settings. Prior to joining the firm, Mr. Renzo was a Partner in the healthcare advisory practice of Baker Tilly LLP. Mr. Renzo also served as Senior Vice President of Investment Banking at Maxim Group LLC and was the Principal of Norwich Consulting Group, a boutique healthcare consulting firm where led transactions ranging from mergers & acquisitions, private placements, secondary offerings, and financial restructurings.

### PROFESSIONAL AFFILIATIONS

American Institute of Certified Public Accountants  
Healthcare Financial Management Association

### EDUCATION

M.B.A. Clemson University  
B.B.A., Accounting, Pace University





# People who know Healthcare, know BDO.

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 [@bdohealth](https://twitter.com/bdohealth)

## ABOUT BDO

BDO is the brand name for BDO USA, LLP, a U.S. professional services firm providing assurance, tax, and advisory services to a wide range of publicly traded and privately held companies. For more than 100 years, BDO has provided quality service through the active involvement of experienced and committed professionals. The firm serves clients through more than 65 offices and over 740 independent alliance firm locations nationwide. As an independent Member Firm of BDO International Limited, BDO serves multi-national clients through a global network of more than 88,000 people working out of more than 1,600 offices across 167 countries and territories.

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