



340B
COMPLIANCE PARTNERS



PROPOSAL FOR 340B DRUG PROGRAM SERVICES

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PROPOSAL FOR SERVICES

Overview

340B Compliance Partners is pleased to submit this proposal for services to support Mangum Regional Medical Center in achieving its goals for improving and maintaining compliance and integrity for its 340B program. 340B Compliance Partners is a pharmacist-owned and operated private company. Guidance and audits are provided by pharmacists and pharmacy technicians to more closely resemble the current HRSA 340B program audits. We are committed to a beneficial partnership to improve your program and will be responsive, dependable, and thorough. Our corporate slogan states our mission and what we provide as your partner: “The guidance you want. The analysis you need.”

The Objective

- Conduct an on-site independent third-party audit for the following registered entity
 - CAH371330 and all registered child sites & contract pharmacies
- Mimic HRSA audit methodologies to prepare client for selection for audit in identifying strengths and opportunities for improvement
- Provide staff and stakeholders education to assist with meeting HRSA expectations
- Determine best partnership plan to move 340B Program forward compliantly while maximizing opportunities.

The Opportunity

- Goal #1: Promote continuous readiness and compliance for the 340B program at Mangum Regional Medical Center
- Goal #2: Identify HRSA audit expectations for your entity
- Goal #3: Make recommendations that maximize the savings and revenue opportunities for the 340B program
- Goal #4: Work with pharmacy staff and others to provide education and guidance for ongoing internal audits and program integrity

The Solution

1. The Client hereby agrees to engage the Consultant to provide the Client with the following consulting services (the "Services")
 - a. Service will include providing a single independent external audit. For each CE, the annual independent audit will be of each universe (i.e., parent, various child sites, entity-owned pharmacies, and contract pharmacy settings). Auditors will mimic the HRSA audit process. Detailed audit process/content for audit is provided confidentially to client and 340B Compliance Partners prides itself in the detail level of the independent audit. A minimum sample from each child site and each contract pharmacy are incorporated to analyze all systems and sites.
 - b. Mimic HRSA audit with level of detail entity desires, including walking through entire process of sending an email to Authorizing Official, pre-audit conference call, data request with comparable deadlines, and finally on-site portion for at least one to two days or longer depending on the scope and sample size with a final report to entity to create a CAP.
 - c. Kickoff meeting with Stakeholders – includes guidance of where each will fit into HRSA audit process
 - d. Verification of all items needed to show program eligibility
 - e. Complete review of Policies and Procedures
 - f. Review of accuracy of HRSA database (OPAIS) for all addresses
 - g. Review of pharmacy accounts to order medications
 - h. Meet with staff to discuss topics an auditor would ask (i.e., meet with buyer to discuss order determination process)
 - i. Demonstration of split-billing system (if applicable)
 - j. Review of patient definition
 - k. Review of provider file
 - l. Eligibility process for provider, credentialing, contracting
 - m. Review of process when a provider is no longer eligible
 - n. Pharmacy Services Agreements reviewed for contract pharmacy relationships
 - o. Samples from all universes will be reviewed:
 - i. Primary entity, Child sites (if applicable), Entity-owned pharmacies (if applicable), and Contract pharmacies will be used for samples [eligible location, eligible provider, eligible patient, verify payer, verify medical record documentation of either administration of medication in mixed-use or of prescription submission to pharmacy, review of billing modifiers if applicable]
 - p. Accumulator functionality is reviewed for each sample selection with replenishment analysis
 - q. Review process for manual changes in accumulator, if applicable

- r. Inventory process: tour of medication storage area and discussion of restocking process, if applicable
 - s. GPO prohibition analysis, if applicable
 - t. Medicare billing analysis for drugs purchased at 340B (CMS SI G/K drugs), if applicable
 - u. Medicaid Carve-in/Carve-out status and appropriate billing per SPA
 - v. Review of minutes of 340B Oversight Committee, or equivalent
 - w. Review of internal audit processes, frequency, documentation, reporting structure
 - x. Material Breach defined in P&P with review of any self-disclosure
 - y. Review of location files for eligibility from billing files
 - z. Hard copy prescription review from contract pharmacies and entity-owned pharmacies
 - aa. Physical site visits to service locations – minimum of one child site and one entity-owned or independent retail contract pharmacy, if applicable to CE
 - bb. Roundtable discussion of things to consider for audit (i.e., if physicians prescribe for themselves, hallway prescriptions for co-workers, etc.)
 - cc. PowerPoint education session provided on-site to audience of choice (arranged in advance for appropriate level of content). Assists in meeting expectations of ongoing education of staff.
 - dd. Exit conference to discuss concerns and answer questions
 - ee. Complete written report of what is going well and what opportunities exist as well as potential risk points within four weeks of exit, provided all data needed has been provided by CE.
 - ff. Assistance with creating a Corrective Action Plan and suggestion for implementation for a period of 45 days after final reports are provided.
2. The Services will also include any other consulting tasks which the Parties may agree upon. As an independent audit client, 340B Compliance Partners will come onsite if requested when actual HRSA audit(s) are conducted for a significantly discounted rate for the duration of any agreement.

Add-On Solutions

1. 340B Compliance Partners Platinum Plan (Monthly Maintenance)
 - a. Includes annual independent audit, as described above.
 - b. Includes having a resource available via phone/email (experienced pharmacist) for questions and guidance throughout the term. This includes reaching out to HRSA/Apexus anonymously on your behalf.
 - c. Fee is parsed over 12 months for ease of budgeting
 - d. Policy & Procedure review with recommendations for edits if gaps identified compared to HRSA expectations, as well as guidance on industry best-practices

- e. Originate (if needed) a facility 340B oversight committee, as well as facilitate meetings with agenda/minutes generation.
 - f. Assist with vendor review, negotiation, and selection
 - g. Review Contract Pharmacy agreements
 - h. Analyze TPA functionality
 - i. Review the ongoing monthly audits performed by your staff
 - j. Provide written reports to leadership
 - k. 10% discount provided for annual independent audit.
 - l. 340B Compliance Partners assigned analyst for your account to complete monthly internal audits of all relevant universes on your behalf
 - m. Analysis of missed opportunities for increased 340B savings
 - n. 25% discount provided for annual independent audit.
2. Referral Prescription Capture Services
- a. Referral Strategist assigned to your account to review potential queue created by TPA(s).
 - b. View access to your EHR to determine required elements of the medical record.
 - c. Will reach out to specialist offices to request care notes be sent to your medical records department, if needed.
 - d. Auditable records readily available.
 - e. Charged as a percent of net CE benefit
3. 340B Data Management Services
- a. 340B ESP Data Submission includes submission of data on a bi-monthly basis. This encompasses generating data extracts from source systems, performing necessary file manipulations, such as NDC filtering, and ensuring the data is submitted on time.
 - b. 340B ESP Data Monitoring including monitoring and resolving issues arising from data submission. This encompasses ensuring all contracted pharmacies are in the appropriate and expected status within the 340B ESP platform and auditing contract loads at the wholesale level.
 - c. 340B ESP Data Analytics including aggregating and data analysis to provide a summarized quarterly report.
 - d. TPA Data File Creation including the generation of data files from source systems to meet the required specifications for the destination Third Party Administrator.
 - e. TPA Data File Automation including the creation of automated processes to generate the needed data files and submit them to the source systems for ingestion.
 - f. TPA Data File Maintenance including any needed file edits secondary to changes in the source or destination system to maintain continuous operation.
 - g. TPA Data File Monitoring including monthly verification of file transmission from source system and ingestion of file at destination system.

- h. Monthly report of financial performance for each CE
- i. Monthly review of outlier accumulations in the contract pharmacy space (both large positive accumulations and negative accumulations) and corrective action taken as applicable.

OUR PROPOSAL

Mangum Regional Medical Center has a desire to be completely compliant with the 340B Program requirements while maximizing the potential savings to meet the 340B program's intent. Mangum Regional Medical Center desires an on-site independent audit of CE CAH371330 to comply with HRSA expectations and ensure programmatic compliance.

Our partnership will assist Mangum Regional Medical Center in meeting their goals for compliance and maximized 340B savings.

Technical / Project Approach

Our goal is to study your 340B program, examine results from any prior HRSA audits to assist with any corrective action, learn about your systems and processes, mimic the HRSA audit with the onsite audit and remote reviews, provide guidance for a strategic ongoing audit plan, and serve as your partner for compliance and integrity.

The actual process for the independent audit will progress as follows:

1. Contracts are fully executed
2. Onsite dates are mutually agreed upon for each audit
3. Schedule the process initiation approximately 60-90 days in advance of onsite
4. CE to choose audience for onsite education offering, if desired
5. Email sent to Authorizing Official to notify of upcoming mock audit
6. Kick-off call is scheduled and held within a few days of AO email
7. Data request will be sent to designated 340B stakeholders with deadlines prior to call and will be reviewed during the kick-off call
8. Designated individual will be provided access to a shared folder to submit data files and all requested documents
9. Two auditors will conduct the onsite portion of the audit

- 10. Detailed mock audit report will be prepared for submission to the Authorizing Official and Primary Contact, or designee(s).
- 11. Assistance with Corrective Action Plan and recommendations for implementation available up to forty-five (45) das after final report sent.

Timeline for Execution

Kick-off for this agreement is upon completion of all signatures unless otherwise negotiated. Key project dates are outlined below. Dates are estimates and are subject to change until a contract is executed.

Annual Independent Audit On-site	Start Date	On-site Date(s)	Duration
Mangum Regional Medical Ctr CAH371330 and all Registered Child Sites & Contract Pharmacies	TBD	TBD	60-90 days advance prep with approximately 1 day on-site.

Supplied Material / Entity Responsibilities

The following materials are to be supplied by Mangum Regional Medical Center for this project. For 340B Compliance Partners to meet project milestones, this material must be supplied on schedule. The due dates included in the following table represent our best estimates based on current proposed dates:

Materials Supplied by Client	Due Date
All materials that would be requested in preparation for HRSA audit – complete list to be provided with kick-off call and communication.	At time of audit. Deadline mutually agreed upon, typically 14-28 days prior to on-site portion of audit.
Staff available for kickoff call and onsite visit to get best result from audit and education	During audit time
Six months of data requests at a designated time to mimic HRSA audit processes	TBD

Expected Results

We expect our proposed solution to Mangum Regional Medical Center’s audit needs to provide the following results:

- Provide the analysis you need with the guidance you want
- Provide a snapshot of program integrity and compliance
- Instill confidence in staff with an educated approach to a robust, compliance 340B program
- Provide feedback for potential findings and opportunities for improvement

PRICING

The following tables detail the pricing for delivery of the services outlined in this proposal. This pricing is valid until 31-Dec-2022. Mangum Regional Medical Center agrees to serve as a reference for 340B Compliance Partners upon successful completion of meaningful services. Other services available for additional fees. A multi-facility discount has been applied below as a Cohesive Healthcare managed facility. Discount is void if less than 80% of offered facilities contract for services (5 facilities offered).

Platinum Plan

Consulting Services / Platinum	Monthly Cost
<p>Annual Independent Audit of CE CAH371330 and all Child Sites, Entity-Owned Pharmacies, and Contract Pharmacies. Availability throughout the term for questions (including anonymous requests to HRSA/Apexus on your behalf). 340B Data Management Services. Other services as needed by CE including: Policy/Procedure review with edits, Oversight Committee facilitation, assist with vendor review/selection, analyze TPA functionality.</p> <p>340B Analyst assigned to CE to complete monthly auditing on your behalf along with a review of missed opportunities for additional program savings.</p> <p><i>Invoiced monthly.</i></p>	<p>\$2,530¹ + Travel expenses*[^]</p>

**Travel expenses for two auditors for onsite portion. Examples of cost containment efforts: Mileage at current government business rate, meals capped at \$60 per day per auditor, economy flights, and will check with CE for any local hotel offers for vendors.*

^Travel expenses can be shared between 2-3 Cohesive Healthcare Hospitals if agreeable by clients and audits are able to be scheduled accordingly.

!If CE chooses, 340B Compliance Partners will train a member of CE staff to complete internal auditing for a one-time fee of \$2,500 and then reduce monthly fee for services to \$2,100 + Travel expenses^ (Gold Plan).*

Referral Prescription Capture Service

Consulting Service	Pricing
<p>CAH371330 and all Child Sites, Entity-Owned Pharmacies, and Contract Pharmacies referral prescription capture services.</p> <p><i>Payment terms negotiable. Invoiced quarterly.</i></p> <p><i>*Consultant and CE to mutually agree around policy/procedure to govern referral prescriptions capture, as well as threshold amount of savings to pursue a given claim. Net benefit example: Copay + Insurance – drug cost – dispense fee</i></p>	<p>17% of CE Net Benefit*</p> <p>*For Gold Plan 14% of CE Net Benefit; For Platinum Plan 10% of CE Net Benefit</p>

QUALIFICATIONS

340B Compliance Partners is focused entirely on the 340B program – this is our business. Your entity needs a responsive, dependable, and thorough partner to comply with all the complexities of the program. Why choose us? We speak the language of pharmacy and 340B. We have been on the side of a covered entity, involved in the detailed operations of 340B and have been audited by HRSA. We have provided consultative services to guide others through a HRSA audit as well as partnered to revamp policies and procedures, analyzed contract pharmacy arrangements and the details of those contracts. Our mission is to help covered entities feel confident in their program integrity without spending a substantial portion of 340B savings on independent audits and consultants to do so. We work with all types of Covered Entities including but not limited to: DSH, SCH, CAH, RRC, CHC, FQHCLA, Ryan White, HTC. Pharmacy personnel are by nature detail-oriented, and you need this level of analysis to



examine your program under a microscope to look for opportunities for improvement proactively.

340B Compliance Partners is comprised of healthcare personnel who have either completed or are in the process of completing the Apexus 340B Operations Certification. All on-site auditors have completed this program. We have greater than 35 years of combined 340B experience. We have a track record individually for being reliable and responsive. With the new Bizzell Group (comprised of pharmacists and technicians) conducting the HRSA audits, our company more closely mimics the process of the actual HRSA audit experience.

CONCLUSION

We look forward to beginning a partnership with Mangum Regional Medical Center and supporting your efforts to improve your compliance for your 340B program. We are confident we can meet the challenges ahead and stand ready to partner with you in delivering an effective and supportive solution.

If you have any questions on this proposal, feel free to contact Sherri Faber at your convenience by email at sfaber@rxconsultantsinc.com or by phone at (304) 964-3903.