



Audit-Ready: How FQHC 340B Compliance Supports Health Centers Through External Audits





Introduction:

The High Stakes of 340B Compliance

For Federally Qualified Health Centers (FQHCs), [340B Program](#)

compliance is essential to sustaining affordable care for patients who need it most. The program allows eligible providers to purchase outpatient medications at discounted prices, helping them stretch resources and improve access for vulnerable populations.

When a HRSA or external audit approaches, every policy, record, and process must be in full compliance. Failure to meet requirements can result in refunds to drug manufacturers or removal from the program. Federally Qualified Health Centers often struggle to keep up with the complex and evolving requirements of the 340B Program.

FQHC 340B Compliance, a dedicated 340B consulting firm, helps organizations address these challenges by offering comprehensive support across all areas of program oversight. Their services include policy and procedure development, compliance reviews, mock audits, contract pharmacy oversight, on-site and virtual staff training, and ongoing program monitoring. By partnering with FQHC 340B Compliance, health centers gain the guidance and structure needed to safeguard eligibility, optimize program performance, and maintain full audit readiness year-round.



LaNika Ellis, Chief Compliance Officer at FQHC 340B Compliance, shared,

“Our external 340B compliance audits help ensure that clients are compliant and 340B audit-ready by identifying risk in areas of eligibility verification, prevention of diversion, and duplicate discounts. With an education-first approach, we provide clear, actionable solutions tailored to each organization’s operations, including optional deep dives into entity-owned pharmacy performance to boost compliance and efficiency.”

In the following case study, we’ll explore the measurable difference that FQHC 340B Compliance’s external audits make for health centers. By examining real challenges, findings, and outcomes, this case study illustrates how an expert, third-party perspective not only strengthens compliance but also enhances program efficiency and long-term sustainability.

The Challenge:

Facing an Audit With Limited Internal Resources

Primary Care & Hope Clinic and PanCare of Florida each turned to FQHC 340B Compliance at pivotal moments in their programs. Primary Care & Hope Clinic was preparing for an upcoming HRSA audit with a demanding request list and limited staff capacity. PanCare of Florida, having already completed a HRSA audit, wanted to strengthen its processes and gain clearer insight into potential risks before the next review.

Both health centers sought support to reduce internal strain, improve documentation, and ensure their 340B programs were built on strong, compliant foundations.

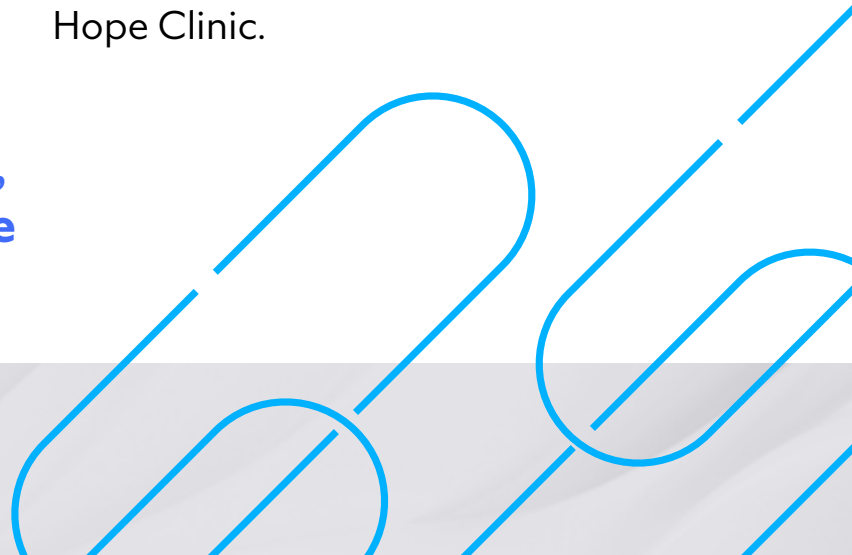
The most significant challenge for PanCare was uncertainty about what an audit might uncover.

“The fear of the unknown – what questions will they ask, what will they focus on, what if I don’t have all of the data they want?”

Although the organization had a prior HRSA audit, it revealed areas for improvement, including consistent documentation and verifying processes with referral providers.

Similarly, Primary Care & Hope Clinic was recently notified of an upcoming HRSA 340B audit, with a detailed request list and a tight timeline. The center’s pharmacy and compliance staff were already stretched thin.

“Our team had been through a previous external pharmacy audit. While we were pleased to have passed, the experience left us realizing that it didn’t give us the best practice recommendations or actionable guidance we needed to truly strengthen and optimize our processes,” said Primary Care & Hope Clinic.





The Partnership: Bringing in FQHC 340B Compliance

Primary Care & Hope Clinic partnered with FQHC 340B Compliance after their annual financial audit.

“We first connected with Michael Gonzalez and were immediately impressed with his expertise and professionalism. That positive experience made it an easy decision to engage his team for our 340B pharmacy program audit.”





The FQHC 340B Compliance team outlined a clear path forward, including flexible audit periods and a review of at least 200 claims across clinic-administered drugs, entity-owned pharmacies, and contract pharmacy claims—double the industry standard. Direct access to TPAs and EHRs minimized the workload for clinic staff, and leadership brought hands-on 340B experience to ensure every recommendation was practical and actionable.

PanCare of Florida engaged FQHC 340B Compliance after learning about the firm through their CEO.

“They specialize in FQHCs,” said the PanCare team. “Their staff includes pharmacists and former FQHC pharmacy professionals who have been through HRSA audits. That level of experience gave us confidence that we were in good hands.”

For Primary Care & Hope Clinic, the depth of insight and practical recommendations made the service stand out.

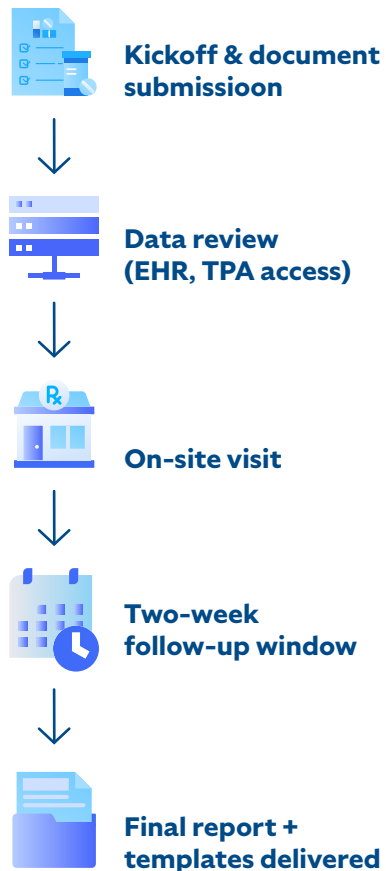
“What really set their audit service apart was the depth of insight and practical recommendations they provided,” said the clinic.

“They far exceeded our expectations, giving us valuable best practices we could immediately apply to strengthen our program. We were so impressed with their approach and ongoing support that we made the decision to continue as a monthly client.”

The Process: From Prep to Audit Day

The audit process began with a kickoff phase to submit requested data and documentation. This allowed auditors to understand 340B operations and identify potential gaps.

Next, FQHC 340B Compliance conducted a thorough data review using access to EHR and TPA systems to confirm patient eligibility, auditable records, and billing compliance. An on-site visit followed, where auditors met with staff, reviewed documentation, and clarified outstanding questions. Clinics then had two weeks to provide additional information or address flagged items.



The process concluded with a detailed audit report and supporting templates, including:

- External Audit workbook
- Policy & Procedures template
- Tracking Clinic Administered Drugs template
- Self-Audit templates
- HRSA audit pitfalls/updates slides
- State-specific Medicaid billing guidelines

Throughout, FQHC 340B Compliance provided guidance, helping clinics feel prepared and confident at every stage.

The Outcome:

Confident, Compliant, and Audit-Ready

The audit proved invaluable for Primary Care & Hope Clinic, revealing areas for improvement.

“With FQHC 340B Compliance’s guidance, we corrected our RX software so that claims have required modifiers, and we updated our 340B eligibility policy to better reflect patient-centered medical home principles.

These changes not only resolved the findings but also gave us greater confidence in the strength and compliance of our program moving forward.”

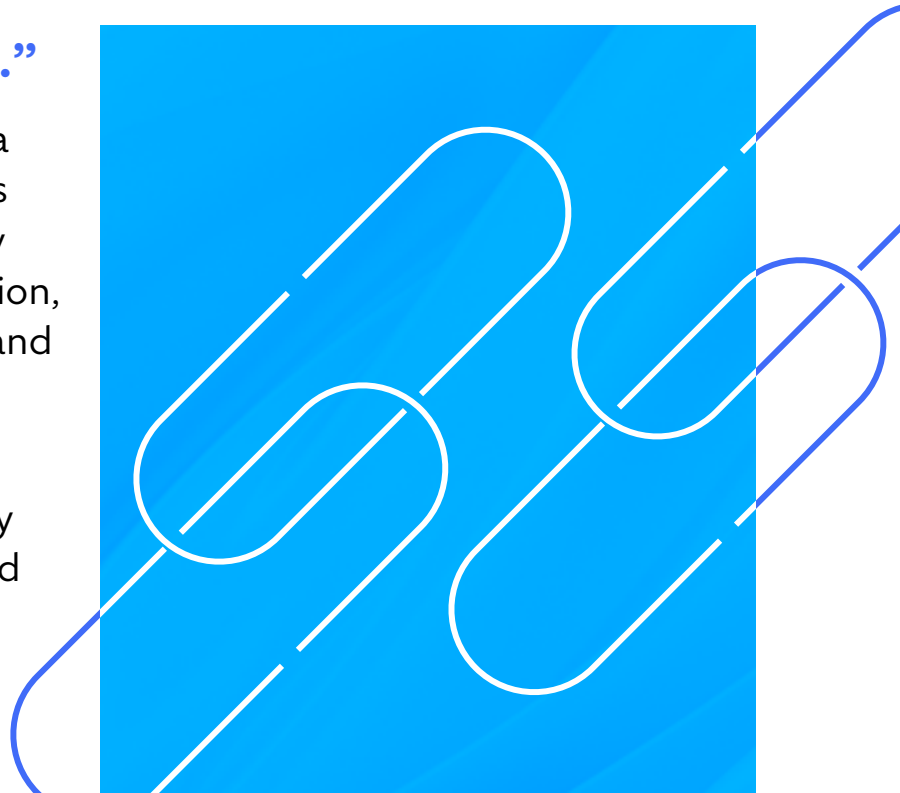
Before partnering, the clinic had a general sense that their processes were in place but lacked certainty about whether their documentation, claims, and policies would withstand a detailed audit.

PanCare of Florida had similar results. While a minor discrepancy appeared with clinic-administered drugs, the team was already addressing it.

“I feel much more confident that if I undergo an audit, we will not only have FQHC 340B Compliance’s support, but also that we will be prepared due to our mock audits,” said a PanCare representative.

“We also have been able to expand our eligible prescriptions, adding financial savings to our program.”

Both health centers emerged with stronger compliance programs, greater operational confidence, and a clear roadmap for continued success.



Lasting Impact: Ongoing Compliance Strategy

Following the audit, Primary Care & Hope Clinic continued working with FQHC 340B Compliance through ongoing monitoring.

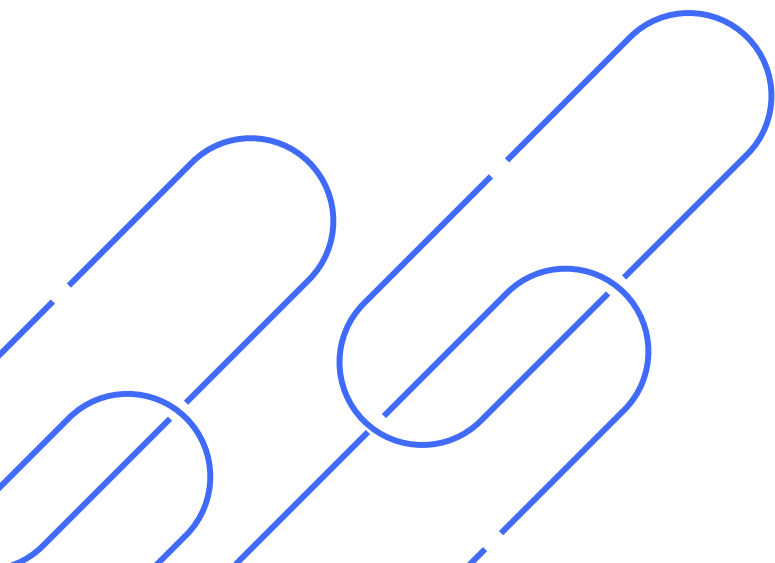
“We asked the team to review our in-house pharmacies to identify opportunities for optimization and efficiency. Their consultants uncovered numerous ways to enhance revenue, strengthen processes, and improve compliance. The value of having such a knowledgeable team supporting our pharmacy operations quickly became clear, which is why we made the decision to continue as monthly clients.”

With these improvements, Primary Care & Hope Clinic now approaches compliance as an ongoing practice, confident in handling future audits.

PanCare of Florida has also maintained a long-term partnership.

“We are now in our third year working with FQHC 340B Compliance. The partnership has allowed us to justify 340B eligibility expansion and better understand what it takes to remain compliant,” said the PanCare team.

Both health centers continue to leverage FQHC 340B Compliance’s expertise to maintain audit readiness, optimize operations, and ensure sustainable benefits for patients and staff alike.





Final Thoughts: Advice for Other FQHCs

The clinic's leadership strongly recommends that other FQHCs seek expert guidance when preparing for an external or HRSA audit.

“The support we receive from FQHC 340B Compliance is indispensable. I honestly cannot imagine operating our 340B program without their expertise and guidance.”

FQHC 340B Compliance continues to partner with health centers nationwide, providing the same expertise and reassurance that turned challenges into success stories. To explore other client experiences and outcomes, visit our [case studies page](#).

