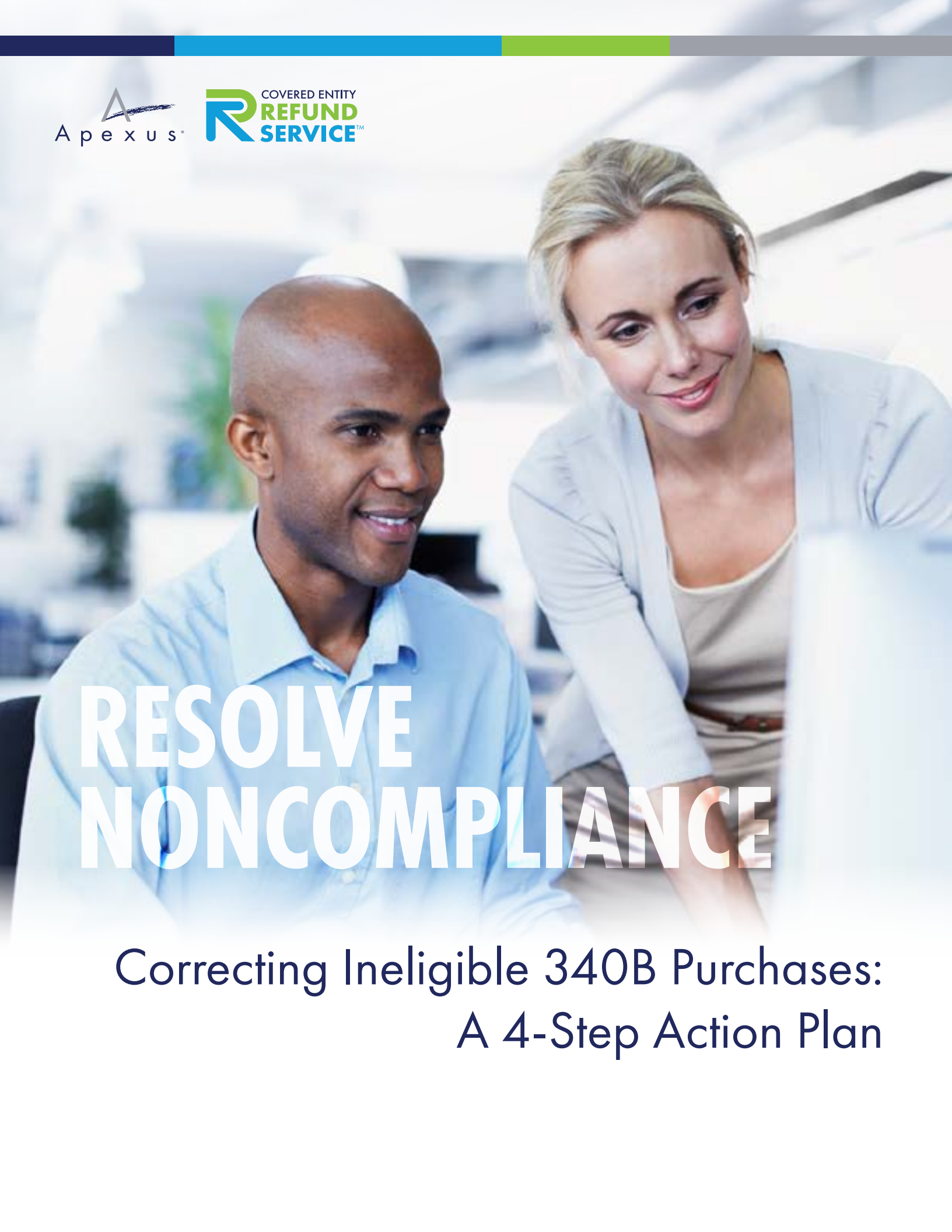


A man and a woman are smiling and looking at a computer screen in an office setting. The man is in the foreground, and the woman is leaning over his shoulder from behind.

RESOLVE NONCOMPLIANCE

Correcting Ineligible 340B Purchases:
A 4-Step Action Plan

STEP 1 Identify Potential Ineligible Purchases

Begin by detecting compliance issues:

Routine Day-to-Day Monitoring

- Negative 340B accumulations in 340B software
- Electronic health record documentation/billing
- Ordering/inventory issues
- 340B software settings

External Audits

- Independent audits
- HRSA audits
- Manufacturer audits

Self-Audits

- Use self-audit tools available at 340Bpvp.com/Tools

Expand the Scope:

Once an issue is identified, assess whether similar purchases were affected and consider conducting a broader review.

STEP 2 Develop a Corrective Action Plan

Follow your organization's established 340B procedures for addressing noncompliance. This may include collaboration with your internal committee or compliance oversight team.

Determine Disclosure Requirements:

Evaluate whether the issue meets your organization's material breach threshold. Refer to the PVP tool [Establishing Material Breach Threshold](#) for guidance.

If non-material:

- Correct the error that led to ineligible purchases.
- Continue to Step 3.

If material:

- Correct the error.
- Disclose the issue to HRSA using the [Self-Disclosure to HRSA and Manufacturer Template](#). (See pages 1–3.)
- Continue to Step 3.

STEP 3 Remediate Noncompliant 340B Purchases

Option 1: Coordinate with the Wholesaler

- Return the product or reclassify the purchase to a non-340B price.
 - **Note:** These options may have timeframe restrictions based on invoice date.
 - Some adjustments may require manufacturer approval before the wholesaler can take further action.

Option 2: Repay the Manufacturer

- Disclose the issue and offer repayment.
- Locate contact information on [340B OPAIS \(Manufacturer Search\)](#) and [MDRP Manufacturer Contacts](#).
- Disclose the issue using the [Self-Disclosure to HRSA and Manufacturer Template](#). (See pages 4–6.)
- Send payment to manufacturers that accept refunds.

STEP 4 Document and Close the Process

Maintain thorough and auditable records of your entire resolution process, including:

- The scope of the issue and assessment steps
- Affected purchases and resolution methods
- Manufacturer communications
- Repayment confirmations and documentation

This documentation demonstrates your organization's good-faith compliance and commitment to the integrity of the 340B Program.