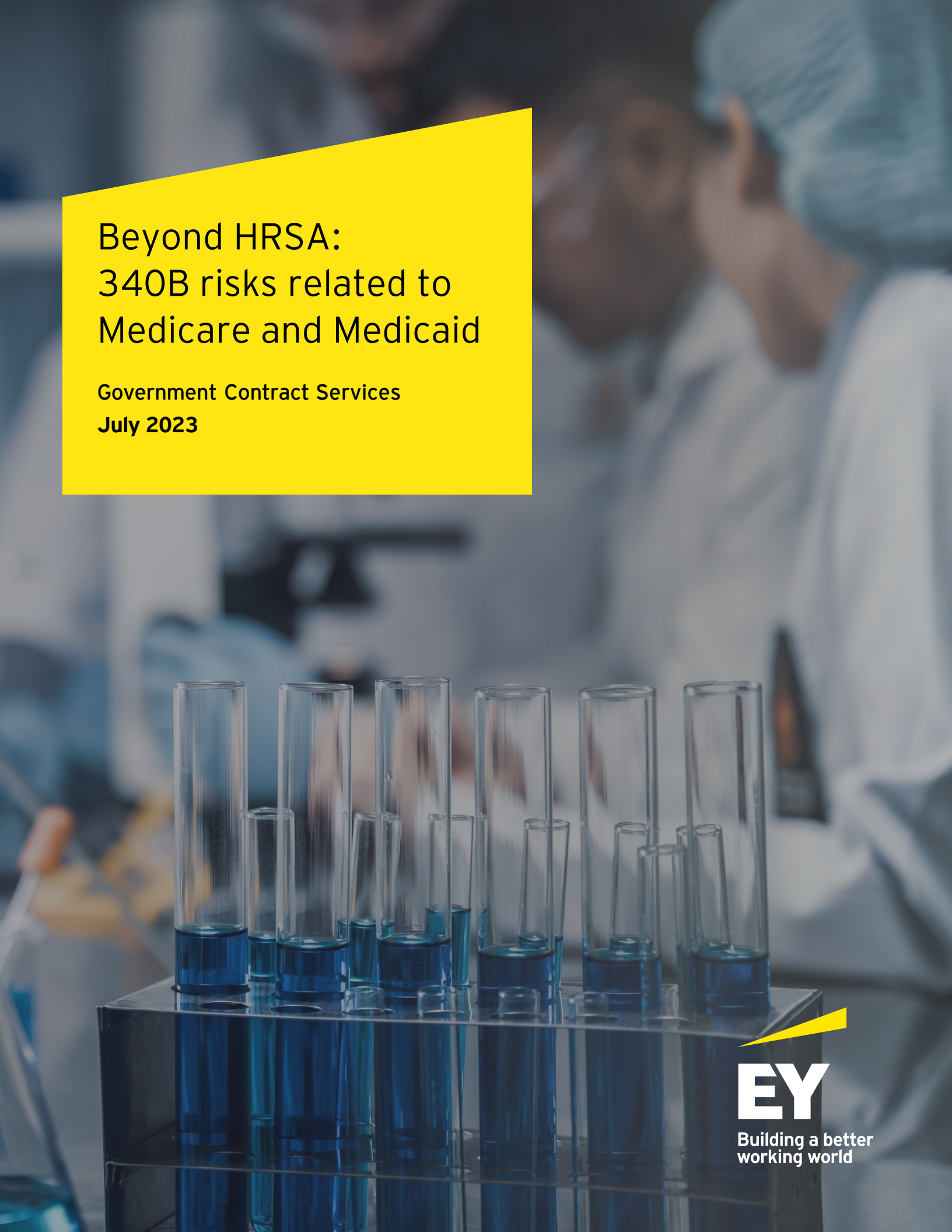

Beyond HRSA: 340B risks related to Medicare and Medicaid

Government Contract Services

July 2023

Building a better working world

340B covered entities focus a lot of compliance efforts on parts of the program governed by the Health Services and Resources Administration (HRSA), but is enough attention being given to non-HRSA compliance obligations? These obligations include:

Medicaid risks

Beyond duplicate discount prevention, state Medicaid programs often impose challenging and cumbersome 340B-specific billing obligations on covered entities. Billing Medicaid incorrectly can cause you to receive Medicaid dollars you are not otherwise entitled to. Billing Medicaid correctly is difficult because each state can have different billing rules, and rules can even differ between retail and institutional settings. What's more, seemingly small errors on government programs can cause you big problems.

340B covered entities should consider the following when evaluating 340B drug billings to Medicaid payers:

1. What states are you billing and what are their rules for 340B drugs?
2. What systems and/or vendors are responsible for making sure that your Medicaid bills are built correctly?
3. Are you keeping up on your institutional and retail pharmacy risks related to Medicaid billing?
4. What steps are you taking to mitigate your risk (e.g., third-party audit)?
5. What operational and procedural challenges are you facing to comply with 340B Medicaid rules?

Medicare risks

Medicare's 340B rules are consistent from state to state but have recently been in flux, which may cause uncertainty about billing obligations and associated risks. Additionally, recent Medicare changes offer financial opportunities that covered entities might not be leveraging.

340B covered entities should consider the following when evaluating their 340B Medicare risk:

1. What processes are in place to establish that your Medicare charges are built correctly?
2. What efforts have you taken to recover underpayments from Medicare Part B and Medicare Advantage Plans?
3. Is access to 340B pricing a factor your covered entity generally considers when enrolling in Medicare reimbursement programs?

Key examples of non-HRSA risks

Claim modifiers are used by Medicare and Medicaid to identify 340B drugs

Billing the NDC actually dispensed is required by many state Medicaid agencies

Federal health care programs bring with them risks of false claims and overpayment liability

Qui tam actions could be brought against covered entities by their own employees

Hospital access to orphan drugs could depend on enrollment status with CMS, not HRSA

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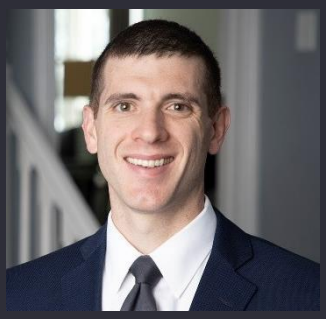

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