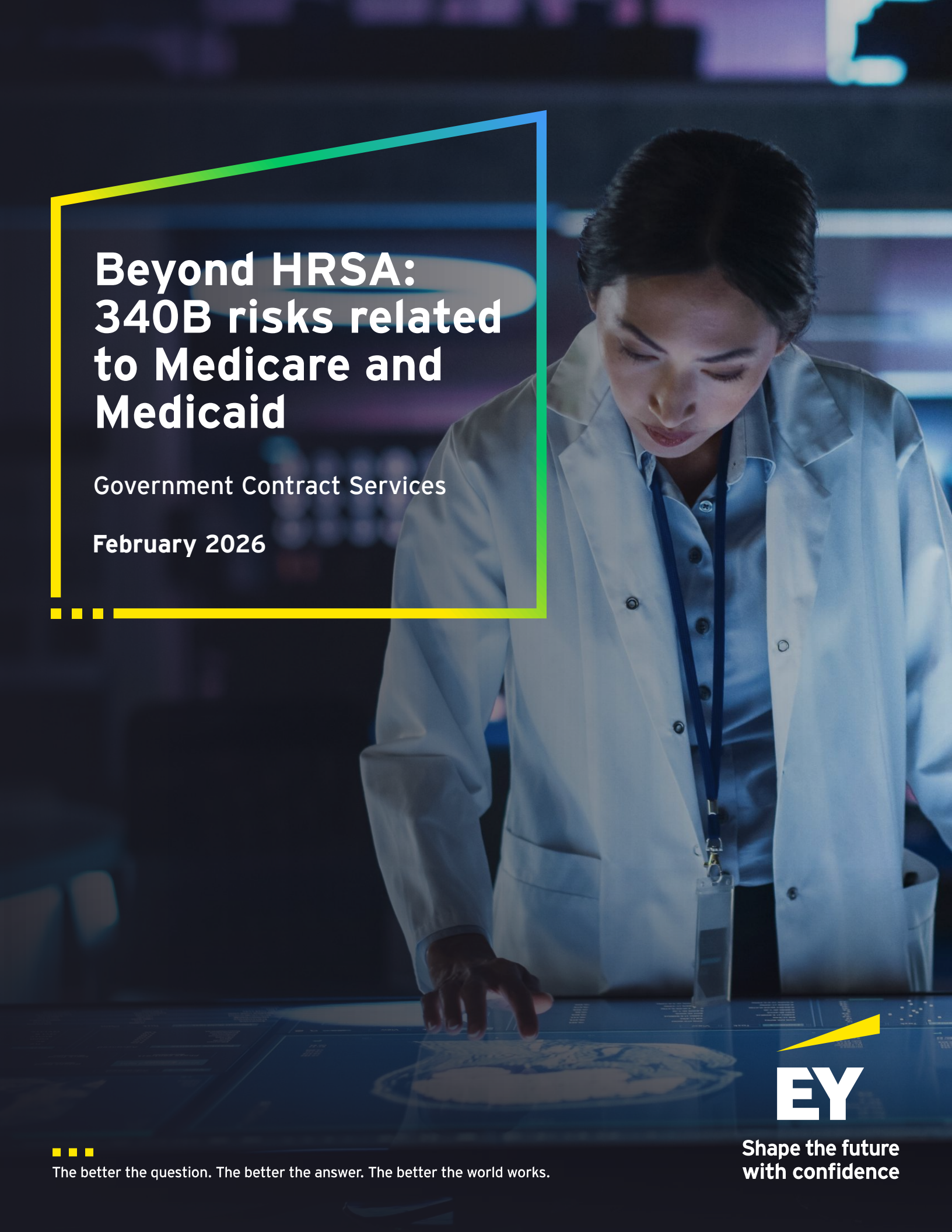

Beyond HRSA: 340B risks related to Medicare and Medicaid

Government Contract Services

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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 formulates their own billing rules. The applicability of rules varies between fee-for-service (FFS) and managed care organization (MCO) plans, and rules 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. For many years, the Centers for Medicare & Medicaid Services (CMS) imposed specific billing requirements on specified 340B hospitals for the purposes of adjusting reimbursement. Those rules were reversed by court order but now CMS is exploring the possibility of reimplementing those rules in a compliant manner. In the interim, the Inflation Reduction Act (IRA) imposed new billing requirements. The confluence of these factors has made it challenging for many billing departments to keep up with the latest rules and guidance.

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. If you a provider that has not historically been subject to 340B specific Medicare billing rules, are you following current Medicare billing requirements?
3. What operational and procedural challenges are you facing with the deduplication of rebates introduced under the IRA?

Key examples of non-HRSA risks

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

Billing the National Drug Code (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.

Government Contract Services
Ernst & Young LLP

Garrett Pape
Principal
+1 312 879 5791
garrett.pape@ey.com

Eliza Biedziak
Managing Director
+1 202 327 8956
eliza.biedziak@ey.com

Matt Newman
Manager
+1 202 327 5714
matthew.newman@ey.com

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