

OUR PRACTICE

340B Drug Pricing Program

The 340B drug pricing program requires drug manufacturers to sell outpatient drugs at discounted rates to certain public and non-profit hospitals that treat high volumes of low-income patients or are located in rural areas and other safety net providers that receive federal grant funding. Hospitals participating in the 340B program include large academic medical centers, public institutions, community hospitals, and small rural facilities serving remote locations. Baker Donelson professionals provide legal services, as well as policy and advocacy assistance, on behalf of hospitals and other health care providers participating in the 340B program and vendors that support them.

Our attorneys advise clients on compliance with the 340B program, including assistance with 340B program policies and procedures, comprehensive compliance reviews, assistance with Health Resources and Services Administration (HRSA) audits, responses to manufacturer inquiries, assistance with and negotiation of contract pharmacy arrangements, and support related to the Medicare and Medicaid payment and billing policies affecting 340B hospitals.

Our policy team members advocate on behalf of hospitals and health systems before Congressional committees with jurisdiction over the 340B Program, including the House Committees on Energy and Commerce and Ways and Means, as well as the Senate HELP and Finance Committees. We also assist hospitals in their evaluation and response to proposed administrative changes that could affect the 340B program.

As policymakers continue to scrutinize the 340B drug pricing program and consider legislative and administrative changes that could diminish the value of the 340B benefit, it is critical that hospitals understand the financial impact the 340B program has on their institution and be able to describe to lawmakers the value of 340B to both the hospital and its patients. We conduct comprehensive reviews of the value of a hospital's 340B program, including calculation of 340B savings and assessment of how the hospital is using savings to support patient care. Our team also helps hospitals identify vulnerabilities, in light of potential changes to the program, providing them with the tools they need to advocate for the protection and preservation of the 340B program.

Legal Services

General 340B Questions

We respond to routine client questions related to 340B program rules and operations, including compliance issues, eligibility questions, contract pharmacy arrangements and negotiations, and Health Resources and Services Administration (HRSA) guidance.

Compliance Reviews

Our team conducts comprehensive and periodic evaluations of hospital compliance with 340B program rules, including reviews of policies and procedures and inventory management systems, as well as assessments of audit readiness.

Draft and Review Policies and Procedures

Our attorneys are available to assess or prepare comprehensive policies and procedures to support covered entity compliance with 340B program obligations as identified in HRSA guidance and audit enforcement.

Audit and Post-Audit Assistance

We assist hospitals selected for HRSA audits with data request responses and preparation for onsite visits. We navigate hospitals through the audit report response process, including audit challenges, submission of corrective action plans, and repayment to manufacturers.

Self-Disclosure Assistance

Our team assists hospitals with the evaluation of compliance issues to determine if a material breach of program compliance or eligibility rules require self-disclosure to HRSA and/or possible repayment to manufacturers.

Eligibility Questions

Our team evaluates 340B implications related to acquisition/building of hospital outpatient departments, including questions about eligibility of new locations to access 340B discounts and effects of Medicare's site neutrality policies for 340B child site eligibility and access to 340B discounts.

Registration Questions

We advise hospitals on HRSA guidance and procedures related to registration of hospitals, child sites, and contract pharmacies, including timing issues related to quarterly registration windows, change requests, and terminations.

Manufacturer Inquiries

Our team assists hospitals in response to drug manufacturer inquiries related to program compliance, ensuring that hospitals work in good faith to address manufacturer concerns without exposing hospitals to potential liabilities.

Advocacy/Policy Services

Congressional Advocacy

Our team advocates on behalf of hospitals and health systems before Congress, including the House Committees on Energy and Commerce and Ways and Means and the Senate HELP and Finance Committees, as well as state Congressional delegations representing client institutions and other members of Congress of strategic value.

Regulatory Advocacy

We assist hospitals and health systems in evaluating and responding to proposed administrative changes that could affect the 340B program, including modeling of financial and administrative impact, drafting of comments on proposed and interim final regulations, and engaging with relevant agencies on an ongoing basis to resolve interpretational disputes. We also monitor legislative and regulatory actions that might put the 340B program at risk, along with efforts to protect institutions from losing eligibility.

340B Value Assessments

Our team conducts comprehensive reviews of the value of a hospital's 340B program, including calculation of 340B savings and assessment of how the hospital is using savings to support patient care. We assist hospitals with the calculation of their 340B savings and revenue to prepare hospitals for the possibility that Congress may require reporting of this information. We also provide advice on how a hospital can describe the value of 340B publicly, including to lawmakers.

Data Analyses

We analyze publicly available data, such as Medicare cost report information and IRS Form 990 Schedule H filings, to quantify a hospital's commitment to serving low-income patients and evaluate the impact of possible eligibility changes to a particular institution. We assess a hospital's current use of 340B, based on determination of patient and drug eligibility, to evaluate how changes to 340B would affect access to 340B savings.



Representative Matters

- Routinely advise hospitals with responses to HRSA audit findings and manufacturer inquiries.
- Address health system 340B steering committee on recent program developments and vulnerabilities.
- Represented hospital with self-disclosure related to 340B program compliance violations.
- Drafted and reviewed 340B program policies and procedures for hospital clients.
- Conducted internal audit of hospital's 340B program compliance.
- Advised hospitals regarding compliance strategies based on political scrutiny and potential program changes.
- Provided strategic policy advice to hospitals to assist with the development of legislative and regulatory advocacy agenda.
- Routinely advise clients on various 340B compliance-related matters, including patient definition, registration, child sites, GPO prohibition, and contract pharmacy arrangements.
- Provided training on 340B program including regulatory overview, compliance issues, program changes, and government enforcement/guidance.