

# 340B Mega-Guidance One-Pager

*As of 9/15/2015*

## Background:

- On August 28, HRSA published the long-awaited [draft of its mega-guidance](#) on the 340B program. The agency is accepting public comments through October 27.
- The mega-guidance addresses a wide range of operational issues, including contract pharmacies, program integrity, and which patients and prescriptions are eligible. While many policies in the mega-guidance reflect current HRSA practice, several are new.
- HRSA lacks the authority to issue regulations on the issues addressed in this document; hence, this document is a “guidance” rather than a regulation. It is unclear to what degree HRSA or the courts will be willing or able to enforce the “expectations” outlined in this document. Regardless, it is still in health centers’ best interests to comply with all the expectations in this Guidance.

## Proposed Policies:

- Prescriptions that are 340B-eligible: The most significant issue for FQHCs and their patients is a proposal to restrict which of their patients’ prescriptions can be filled using drugs purchased under 340B. Specifically, **the mega-guidance would prohibit FQHC patients from accessing 340B drugs for prescriptions written by non-FQHC providers, including those written by specialists and when they are discharged from the hospital.**
  - NACHC is drafting official comments to HRSA, pointing out how this proposal will be harmful to both FQHC patients and to FQHCs’ financial sustainability.
- Medicaid managed care: The mega-guidance permits FQHCs to carve-in Medicaid managed care patients, and to decide whether to carve in or out on an MCO-by-MCO basis. However, if an FQHC wants to carve in Medicaid MCO patients at a contract pharmacy, either the state or the MCO must sign a contract with the FQHC and the pharmacy agreeing to the carve-in, and the plan for avoiding duplicate discounts.
- Contract pharmacies: The Guidance does not limit how many pharmacies an FQHC can contract with. However, the FQHC must conduct an annual independent audit of all contract pharmacies, and conduct internal reviews on a quarterly basis.
- Responsibility for compliance: The guidance repeatedly states that the FQHC is fully responsible for ensuring compliance with all program rules, including those involving contract pharmacies.
- Audits: FQHCs must keep “auditable records” for at least 5 years. Self-audits are not required, but strongly encouraged.