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340B Drugs May Be Available in Non-PBDs; Signs May Trip Up PBDs

By Nina Youngstrom

Hospitals that stick with provider-based status despite the erosion in reimbursement because they rely on 340B drug discounts may now have some wiggle room. The HHS Health Resources and Services Administration (HRSA) indicated it has limited enforcement authority for its policies, opening the door to 340B drugs at outpatient clinics that aren't provider-based departments (PBDs), an attorney said.

"The question is whether or not you need to be in provider-based space to qualify for the 340B drug discount," attorney Andrew Ruskin said March 23 at the American Health Law Association's Institute on Medicare and Medicaid Payment Issues.[1] HRSA's acknowledgement in audits of 340B compliance that its hands are somewhat tied creates an opening "to say there maybe is room to not be provider based. It depends on your interpretation of 340B provisions."

The cost-benefit analysis of a PBD may change if it isn't always the price of admission to the 340B drug-discount program. "Not everyone will think it's worth it to be provider based," Ruskin said. "Maybe there are other ways to get 340B drugs. When you look at the compliance costs of being provider based versus the advantages, you may just say to heck with it. That's your choice. You can interpret the HRSA requirements the way you think are consistent with the program."

Another thing to factor in: CMS cut reimbursement for 340B drugs in 2018 from average sales price (ASP) plus 6% to ASP minus 22%. The American Hospital Association challenged the payment cut all the way to the Supreme Court, and a decision that could restore the payments is due this term, probably sometime in June.

There also are larger forces at play in terms of the way hospitals deliver services because of the changes ushered in by the COVID-19 pandemic, said attorney Larry Vernaglia, with Foley & Lardner LLP, who also spoke at the conference. When the pandemic hit, CMS gave hospitals a lot of flexibility to provide services in any location that met the conditions of participation and to partially relocate PBDs, he said. For example, outpatient services are now delivered to patients' homes for full outpatient payments and in hospitals without walls (temporary expansion sites), including the ultimate extension to the Acute Hospital Care at Home program, Vernaglia said. Even after the public health emergency, "the combination of adjustments and some of the reimbursement pressures already in the system should make hospitals think more creatively and broadly about their sites of service and how they deliver services," Vernaglia said. "It's not just inpatient and outpatient anymore."