

Pharmacy Benefit News

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340b - Who is Eligible? Who Can Prescribe?

A Commentary

We have received many questions about 340b prescriptions. The questions generally focus on eligibility for patients and prescribers. The Department of Health and Human Services (HHS) has provided guidance. The following quotations provide some clarification to Section 340B(a)(5)(B) of the PHSA:

- HHS is proposing a clarified definition of patient for purposes of the 340B Program. In its clarification of what constitutes a violation of section 340B(a)(5)(B) of the PHSA, HHS also is proposing its interpretation of section 340B(a)(5)(D) of the PHSA. Section 340B(a)(5)(D) of the PHSA states a covered entity violating section 340B(a)(5)(B) of the PHSA shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug.
- An individual will not be considered a `patient' of the entity for purposes of 340B if the only health care received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.
- An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under Title XXVI of the PHSA will be considered a `patient' of the covered entity for purposes of this definition if so registered as eligible by the State program." (61 FR 55157-8, October 24, 1996).
- HHS interprets the statute such that a 340B eligible patient receives a health care service from the covered entity, and the covered entity is medically responsible for the care provided to the individual. An individual who sees a physician in his or her private practice which is not listed on the public 340B database or any other non-340B site of a covered entity, even as follow-up to care at a registered site, would not be eligible to receive 340B drugs for the services provided at these non-340B sites. The use of telemedicine involving the issuance of a prescription by a covered entity provider is permitted, as long as the practice is authorized under State or Federal law and the drug purchase otherwise complies with the 340B Program.
- An individual will be considered a patient of a covered entity if the health care service received results in a drug order or prescription. The use of telemedicine, telepharmacy, remote, and other health care service arrangements (e.g., medication therapy management) involving the issuance of a prescription by a covered entity is permitted, as long as the practice is authorized under State or Federal law and otherwise complies with the 340B Program.

We can expect 340b clarifications to continue as audits occur that identify problems or unique variances from the HHS expectations of 340b coverage.

Analytics at Work: A Real World Example

It's All Formulary...

A public Medicare/Medicaid Health Plan needed a bridge file for matching medication therapeutic categories with the RxCUI and RxNorm. It was necessary to match the medication NDCs to the RxCUI that would be used for developing and maintaining their formulary.

Pro Data Analytics produced the bridge file and maintains it on a monthly basis. New medications and changes are produced and matched when necessary to ASHF, GPI and GCN codes. The support included brand, generic and other categories of medications, and support for classifying, and reclassifying medications to match coding from other therapeutic category systems. The language used for drug naming obeyed the SNOMED classification when appropriate.

The result was a significantly reduced need for resource support since the process was mostly digital. The Health Plan was able to communicate their formulary to all users and to make immediate changes when necessary without clinical support teams.

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Oxycodone for Kids?

A Commentary

The Food and Drug Administration (FDA) approved oxycodone hydrochloride (OxyContin—Purdue Pharma) for children as young as 11 years who need "daily, round-the-clock, long-term" pain relief that cannot be treated adequately with other medications. Not unsurprisingly, there was controversy. Some pediatricians loved it, but FDA critics didn't like expanding the availability of opiates for kids.

The FDA defended its actions by saying that "the approval was not intended to expand the use of opioids in children, but rather to give doctors better guidelines about how to use oxycodone hydrochloride safely in pediatric patients". Effectively the FDA was trying to apply evidence-based medicine guidelines. The man-made problem with opiates is not trivial, but the efforts to reduce the problem have added their own level of controversy. The efforts to apply evidence to therapeutic regimens has been a movement since at least the 1970's.

Evidence-based guidelines were a factor in Medicare, Medicare Part D, the Affordable Care Act (ACA) and the AHRQ. Interestingly, evidential guidelines have created their own brand of controversy based on the stakeholder vantage point, commercial interests, and the quality of the research supporting the guidelines. The ultimate goal of such guidelines is to try to ensure the correct population is provided the treatment, while the incorrect or less studied population does not.

The age of physicians doing whatever they want is over. It was actually over years ago. Now we appear to be in a time of evidential reviews and debates over their merits. Hopefully, as a result, patients will benefit.

Source: "Why FDA approved oxycodone hydrochloride for kids as young as 11 years", Washington Post (09/08/15) Dennis, Brady

Heart Attacks and Stroke May be Dependent on Cardiac Age, Not Chronological Age

A Commentary

The Centers for Disease Control (CDC) reported that "Most adults in the United States have a heart age that is much older than their chronological age, putting them at risk for heart attacks and stroke". The CDC looked at several metrics including racial, sociodemographic, and regional disparities in heart age among adults aged 30–74 years.

The result was that an estimated 69 million adults have heart ages older than their actual age. The variance was 7.8 years for men and 5.4 years for women. The CDC noted that "There were statistically significant differences in heart age in terms of race/ethnicity, socio-demographics, and region".

The age groups of particular concern are those people who are chronologically near their early 50's, or younger people who have one or more cardiac risk factors.

This provides an opportunity for all health care professionals to counsel individuals about their heart age and to motivate people to lead more heart healthy lifestyles.

Source: Most Americans' hearts are older than their age

Morbidity and Mortality Weekly Report (09/01/15) Yang, Quanhe; Zhong, Yuna; Ritchey, Matthew, et al.



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JCode Calculator™

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