July 13, 2023

## ILLINOIS HEALTH AND HOSPITAL ASSOCIATION M E M O R A N D U M

SUBJECT: CMS Proposed 340B Payment Remedy

On July 11, the Centers for Medicare & Medicaid Services (CMS) <u>proposed</u> a 340B payment remedy in response to the U.S. Supreme Court Decision in *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022). The case focused on whether CMS has the authority to make cuts to the 340B program under the Medicare Outpatient Prospective Payment System (OPPS). The Court found that CMS unlawfully underpaid hospitals for 340B-acquired drugs when it changed its payment policy from average sales price (ASP) plus 6% to ASP minus 22.5% in calendar year (CY) 2018.

CMS' proposed remedy is to provide 340B-enrolled hospitals with a one-time, budget neutral lump sum payment. CMS proposed to pay hospitals the difference between payments it made for 340B drugs from CY 2018 through Sept. 27, 2022, and what payments would have been had the 340B payment policy not changed.

CMS estimates that 340B hospitals received approximately \$10.5 billion less in 340B drug payments from CY 2018 through Sept. 27, 2022. 340B hospitals have already received approximately \$1.5 billion in remedy payments through reprocessed claims for 340B drugs provided from Jan. 1, 2022 through Sept. 27, 2022. This leaves approximately \$9 billion that CMS will repay to 340B hospitals upon finalizing this rule. This total includes money that would have come from Medicare beneficiaries via cost sharing. CMS emphasized that Medicare will cover the cost of these beneficiary payments, and hospitals may not bill beneficiaries for coinsurance on remedy payments.

CMS reimburses hospitals for 340B-acquired drugs under the OPPS. Because the OPPS is a budget neutral system by statute, CMS increased non-drug item and service payments to all OPPS providers for CY 2018 through CY 2022 when it implemented the 340B payment policy of ASP minus 22.5%. This resulted in additional payments to all OPPS hospitals for non-drug items and services. CMS believes that as it is now making additional payments to affected 340B hospitals, it must correspondingly offset OPPS payments to maintain budget neutrality.

CMS proposed prospectively offsetting OPPS payments for non-drug items and services by \$7.8 billion to maintain budget neutrality. CMS explained that hospitals spent more on drugs than it expected when it originally made budget neutrality adjustments between 2018 and 2022 to OPPS payments for non-drug items and services. Therefore, the Trust Fund and beneficiaries saved more money from cutting the rates paid for 340B drugs than was paid for non-drug items

and services in its budget-neutrality adjustment to offset the savings. Thus, the proposed budget neutrality adjustment is lower than the lump sum payment amount CMS proposed paying to 340B hospitals.

To achieve budget neutrality, CMS proposed reducing all payments for non-drug items and services to all OPPS providers by 0.5% percent each year until the total offset is reached. CMS proposed implementing this adjustment in CY 2025, and believes it will take approximately 16 years to reach the estimated \$7.8 billion it must recoup to achieve budget neutrality.

CMS currently estimates that Illinois 340B hospitals will receive a lump sum payment of approximately \$335 million in response to this proposed remedy. CMS will instruct Medicare Administrative Contractors (MACs) to make lump sum payments after finalizing this rule, with payments issued to 340B hospitals within 60 calendar days of the MACs receiving instructions. CMS anticipates MACs will begin making payments by the end of CY 2023 or beginning of CY 2024.

Comments on this proposed remedy are due to CMS by Sept. 5, and may be submitted through the Federal Register.