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July 8, 2019

Lisa Wright-Solomon
HRSA Information Collection Clearance Officer
Room 14N136B
5600 Fishers Lane
Rockville, MD 20857
Submitted electronically to paperwork@hrsa.gov

Re: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915-0327-Revision

Dear Ms. Wright-Solomon,

The Children's Hospital Association (CHA) appreciates the opportunity to provide comments on Health Resources and Services Administration's (HRSA) proposed changes to the 340B Drug Pricing Program (340B Program) forms. CHA represents over 225 children's hospitals who provide care to children across the country. Children's hospitals support the 340B Program and its mission to stretch scarce resources as far as possible to reach more patients and provide needed services. We welcome any chance to partner with HRSA to enhance the 340B Program.

In Appendix A we provide specific comments on the enrollment and re-certification forms. We also seek clarification on certain aspects of the forms. For ease of your review, we grouped our comments and questions according to the names of the PDF files we received from HRSA. If you require any clarification or if we can be of further assistance, please do not hesitate to contact Steven Chen at steven.chen@childrenshospitals.org. Once again, we appreciate the opportunity to provide feedback and look forward to future opportunities to work to improve the 340B Program.

Sincerely,

A handwritten signature in black ink, appearing to read 'M. James Kaufman'.

M. James Kaufman, PhD
Vice President, Public Policy

Appendix A

340B Registration Children's Hospital –5.14.19.pdf

1. Please change the spelling of “CHILDEN’S HOSPITALS” to “CHILDREN’S HOSPITALS” in the title.
2. The instructions in the Registration form specified that a complete registration package must include registration information, compliance certification, and certain documents if the hospital is alerted. The instructions later add that the entire package must be submitted on the same day to be considered complete. Can HRSA provide more details as to how the alert process will operate and the timing of the alerts? Will the hospital receive an alert on the same day it submits the registration information? Will HRSA provide sufficient time for hospitals to respond to the alert on the same day?
3. Under Section I, in addition to the Medicare Provider Number, HRSA should consider collecting the National Provider Identifier for the hospital. We believe this will align with the information requested under Section IV, Medicaid Billing.
4. Under Section II, please confirm that the heading “A. Government Official who can certify the hospital’s classification” should not be “D. Government Official who can certify the hospital’s certification.”
5. Under Section II, “A. Government Official who can certify the hospital’s classification,” is it sufficient if the hospital provides a government official with knowledge of the hospital’s classification? Or does HRSA require the government official to meet additional qualifications, and if so can HRSA explicitly specify?

340B Registration– Outpatient Facility – 5.14.19.pdf

6. We have a similar question on the alert process described in the instructions that we raised in (2) above.
7. Can HRSA clarify when this form needs to be completed? Is it required only when an outpatient facility is registering for the first time or must the hospital continuously submit this form at each re-certification?

340B Recertification Children's Hospital –5.14.19.pdf

8. Instead of “340B PROGRAM REGISTRATION FOR CHILDEN’S HOSPITALS,” we believe the title should be “340B PROGRAM RECERTIFICATION FOR CHILDREN’S HOSPITALS.”
9. We have a similar question on the alert process described in the instructions that we raised in (2) above.
10. We note that the instructions in the Recertification form appears to be incomplete.
11. Our comments in (3), (4), and (5) above are repeated here.

340B Participant Change Request–Revised.pdf

- Can HRSA provide guidance on when this form needs to be completed? How much time does a hospital have to report any change?