August 25, 2014

Ms. Mary Wakefield, Ph.D., R.N.
Administrator
Attn: Juanita Grabner, Special Assistant to the Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

RE: Request for Tribal Consultation on 340B Drug Pricing Program

Dear Administrator Wakefield:

The members of the Tribal Self-Governance Advisory Committee to the Indian Health Service (TSGAC) are requesting that the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) engage in Tribal consultation on the pending proposed rule changes for the 340B Drug Pricing Program.

On April 9, 2014, the United States Office of Management and Budget (OMB) published a notice indicating a proposed rule was forwarded by HHS/HRSA to OMB for review (HRSA RIN 0906-AB04). As described on the OMB Website, “This proposed rule would establish comprehensive 340B Drug Pricing Program requirements for participating covered entities and manufacturers.” Further, the proposed rule is described as being “economically significant.”

Given the importance of the 340B program to the mission of Indian health care programs, we are concerned that the proposed rule may impact the ability of Indian health care programs to meet the needs of its beneficiaries. To date, Tribes and Tribal health organizations have not been consulted on the changes being proposed.

Please contact Terra Branson at terrab@tribalselfgov.org to discuss the scheduling of Tribal consultation on this matter. Thank you in advance for your attention to this request.

Sincerely,

Chief Lynn Malerba, Mohegan Tribe
Chairwoman, TSGAC

cc: Krista Pedley, Director, Office of Pharmacy Affairs, HRSA, HHS
Dr. Yvette Roubideaux, M.D., M.P.H. Acting Director, IHS
P. Benjamin Smith, Director, OTSG, IHS
TSGAC and Technical Workgroup