Comments on the SECURE 340B Act

- Appreciate the patient definition, clearinghouse and contract pharmacy language and moratorium on rebate models as well as codifying 340B pharmacy protections.
    - We applaud the language that would codify 340B pharmacy protections by requiring drugmakers to continue offering 340B pricing even when the drugs are dispensed through contract pharmacies and by banning payers, pharmacy benefit mangers, health plans and others from discriminating against covered entities.
    - We support the establishment a 340B Data Clearinghouse – currently, manufacturers are requiring 340B covered entities to submit data through third parties that force covered entities to submit to onerous, one-sided terms and conditions that force covered entities to provide sensitive patient information while there is no accountability for the manufacturer or the third party for a data breach. A clearinghouse established by HHS would establish clear authority under HIPAA for data submission while also ensuring data security.
    - We oppose a rebate program which would allow manufacturers to impose its own criteria for determining whether individual purchases are eligibility for the discount after the fact and require covered entities to purchase drugs at prices higher than those paid by any hospital system (including those who are not eligible for the discount) while waiting for reimbursement of a discount that may never come.

Problematic…

- Charity care reporting would add more costly bureaucracy. Hospitals already report "community benefits" which includes charity care in the publicly available Schedule H on the 990 form.

- Same for expanded compliance requirements… For example, requiring hospitals to document drug costs and reimbursement for the drugs is difficult to accomplish when the pricing and reimbursement fluctuate by payer and time. Additionally, requiring 340B entities to show how they are using savings for the provision of charity care, community benefits, or subsidized health care adds costs. Charity care and community benefit programs are not specifically tied directly to the amount of savings received through the 340B program and savings are not directly allocated toward specific budget or project categories. Not all technology vendors currently supporting 340B hospitals track this data, requiring different IT builds and potential different technology implementation.

- Tying 340B prescriptions to Medicare would exclude telemedicine and medication management therapy (MAT).

- Directing hospital finance assistance and patient billing practices is government overreach. Patient financial assistance policies applicable to 340B policies should be aligned with those already required of 501(r), aligning federal requirements so as not to create two varying standards. Baptist Health has a robust charity care policy.

- Requiring a direct link to the outpatient health care service and the prescription would eliminate the use of the 340B discount for discharge prescriptions. This is detrimental to patients and hospitals because 340B hospitals use 340B savings to deliver patient's prescriptions right to their beds while awaiting discharge – "beds to meds." This has significantly increased patient compliance with post-discharge medication plans, reducing future hospital readmission and thereby reducing costs to insurers, including Medicare and Medicaid.

- Requiring the covered entity to maintain auditable health records which reflect the provider-patient relations and limit qualifying prescribers to those that are employed directly by the hospital or an affiliated physician organization would exclude physicians who have medical staff privileges at a 340B hospital where the physician renders professional services.

- Restricting qualified referral scripts to only covered entity federally qualified healthcare centers, critical access hospitals, and sole community hospitals to qualify prescriptions will eliminate the ability for safety net hospitals to include scripts written by independent community specialists, which include high-cost cancer treating drugs and other important medications and referral networks where the covered entity cannot demonstrate direct and ongoing clinical responsibility for the drug-related care, but has overall responsibility for other treatment being provided to the patient.

- Requiring child sites to maintain a new community vulnerability standard to maintain 340B eligibility is unnecessary since 340B hospitals already must meet an overall DSH percentage or RRC (rural referral center) criteria. This would eliminate many child sites, such as infusion centers that hospitals have established in areas closer to patient homes through savings generated through the 340B program.