DISCUSSION DRAFT REGARDING STATE AND FEDERAL 340B REFORM EFFORTS

State reform efforts:

The CHC Reference Spreadsheet (aka "Mega-Spreadsheet) tabs that reference State 340B Laws and State 340B Bills provide an excellent baseline of the provisions that would be included in model legislative language. Those are included in the far left column and include:

- General 340B non-discrimination provision.
- Protects all types of 340B safety net providers from discriminatory arrangements.
- Prohibits discriminatory practices by:
    - PBMs;
    - Other third parties – i.e. insurers, TPAs, etc.; and
    - Contract Pharmacies (chain and independent).
- Prevents PBMs from requiring modifiers or other identifiers of prescriptions filled with 340B.
- Specifically prohibits chargebacks or other adjustments based on 340B eligibility.
- Prohibits discrimination that interferes with the patient's choice to receive prescriptions from a 340B covered entity.
- Prohibits PBMs from restricting access to pharmacy networks based on whether those networks based on whether it dispenses 340B drugs.
- Requires manufacturers to ship to contract pharmacies. **I would suggest that this provision be strengthened to include language that clearly codifies contract pharmacy as an allowable distribution channel for prescriptions filled with 340B.**
- Addresses Medicaid managed care drugs. **More specifically for South Carolina: continues to include pharmacy care in the MCO capitation rate and allows safety net providers to retain a reasonable contribution margin from prescriptions filled with 340B purchased drugs.**

Of all the bills that have been passed, Louisiana is the gold standard thus far. Though Arkansas' bill has resulted in the reversal of some contract

pharmacy restrictions, it was drafted in a short period of time and does not represent a full-blown consensus proposal. In contrast, the Louisiana bill was 2 years in the making and, as a result has been built on a solid foundation of consensus across many stakeholders.

Federal reform discussions:

In all ongoing discussions at the federal level, at a minimum the following topics are included in proposed policy framework:

- Increasing HRSA's authority over the program, establishing a user fee to support additional oversight, and granting direct hire authority.
- Increasing program integrity requirement including enhanced guidance and increased audits. Within the gestalt of increased program integrity is ensuring that covered entities truly function as safety net providers.
- Transparency is significant to all discussions including robust reporting related to covered entity eligibility, patients served, and allocation of 340B contribution margin to health care programs and services.
- Preventing duplicate discounts – those possible due to both statutory and voluntarily negotiated rebates – and most suggest this is best accomplished through a national data clearinghouse operated by an independent contracting entity.
- Prohibition on discriminatory practices and contracting due to 340B covered entity status.
- Codifying contract pharmacy as an allowable distribution channel for prescriptions filled with 340B, though many in discussions at the federal level hope to establish both numeric and geographic boundaries that limit the use of contract pharmacies. All discussions include an imperative for robust oversight and compliance of contract pharmacies.
- An imperative that all 340B covered entities will implement patient assistance programs that apply to all 340B distribution channels.
- Tightening up the eligibility requirements for each covered entity type to ensure only those operating as true safety net providers may participate in the program. A strong focus in this area is the current loose eligibility requirements for hospital child sites. Another strong

area of focus is eligibility passed on through in-kind services rather than direct patient care services.

- Following the decision in the Genesis case, patient definition has risen to the top of the priority list in most discussion groups. The biggest challenge in this area is finding a reasonable allowance for referral prescriptions being filled with 340B in order to promote continuity of care across the continuum.