

SNHPA is Striving to Improve IPAPs

By Judy Fox, CIS Director, US Commercial Compliance

I recently had the pleasure of interviewing Rita Baskett, Director of Pharmacy and Educational Services of Safety Net Hospitals for Pharmaceutical Access (SNHPA) and a member of their Patient Assistance Programs (PAP) and Institutional PAPs (IPAPs) Advisory Committee. SNHPA is an organization of over five hundred (500) public and private hospitals and health systems throughout the United States that participate in the Public Health Service 340B discount program. SNHPA monitors, educates, and serves as an advocate on federal legislative and regulatory issues related to drug pricing and other pharmacy matters affecting member providers. SNHPA is dedicated to creating new opportunities for members to save on pharmaceuticals and improve access to pharmaceutical care. Individual application PAPs require each patient to be approved prior to the hospital receiving the medications. IPAPs allow a hospital to receive the drugs through bulk replacement programs and administer them to eligible patients. Rita, who oversaw the PAP program at Carolinas Healthcare System for 6 years, shared the Committee's concerns regarding the future of IPAPs in SNHPA hospitals across the country.

The PAP Advisory Committee reached out to pharmaceutical manufacturers through one of the industry's primary IPAP auditors ("vendor") earlier this year in an effort to address the concerns over IPAP requirements and audit practices. The goal was to bring members' concerns to the attention of manufacturers in the hopes of reaching an amicable solution to what the Committee sees as a cause for action.

SNHPA members have voiced concern over the methodology for the requirements for hospitals to participate in IPAPs, and specifically IPAP audits. The current requirements for participation are not standardized among drug manufacturers and member hospitals are experiencing a wide range of audit activities that prove to be onerous and difficult to accommodate. The audit requirements are especially taxing, given the fact that hospitals do not have dedicated resources available for audits. As a result, as hospitals question the value of participating in IPAPs, they are withdrawing from the programs and are relying on the individual PAPs to bring medications to needy patients.

"Hospitals really need the IPAP programs to become more manageable," Rita pointed out as she outlined some of the concerns, "SNHPA believes the two sides can reach an amicable solution that will satisfy the drug manufacturers and their regulatory responsibilities without taxing the hospital resources." She provided insight into some of the challenges as well as recommended solutions to the audit process:

Concerns:

- The documents being requested during an audit include documentation that is repetitive to the same information hospitals have to submit in order to qualify for IPAPs. As an example, in order to qualify for IPAP participation, a hospital has to submit its relevant policies and procedures for managing the program and provide updates whenever the documents are revised. Auditors are requesting the same documents during an audit. SNHPA members feel that their submitted documents should be retained and reviewed prior to the on-site audit as a means to facilitate a more efficient audit process.
- The document requests during an audit are not consistent. In some cases, hospitals are permitted to submit documents electronically prior to the on-site audit, and others require hospitals to present documents to the auditors on-site, adding inefficiencies to the process, and still others require information such as dispensing records to be viewed on the hospital computer screens and do not permit the hospitals to provide printouts for the audit review. In addition, hospitals feel that some documents requested are not relevant to the audit or managing an IPAP. When document requests extend beyond the management of the IPAP, hospital members must obtain it from other resources within the hospital, increasing the burden. As an example, the following documents have been reported as requested during an IPAP audit: hospital floor plans and security systems; individual pharmacist's license; and hospital financial statements.
- Auditors have increased the number of patient files to be tested during an audit, yet the increase in the sample size is not directly related to the volume of patients.
- The length of an audit varies from two (2) days to a full week, without the timing of the audit aligning to the IPAP activities or patient volume. Since

hospitals have limited resources and space for audits, the audit scope should reflect a reasonable rationale behind the need for a week long audit.

- Drug manufacturers require specific IPAP policies and procedures, some drug specific policies and procedures, rather than policies generally applicable to all IPAPs.
- The IPAP renewal process is becoming increasingly difficult, including submission of the same policies and procedures submitted during the application and audit processes. Additionally, the eligibility period is very short while the renewal process is very long, resulting in a renewal cycle that is extremely inefficient and time consuming.

Suggestions for improving the audit process:

- Standardize the audit process, specifically, the methodology for document review should allow auditors to confirm that documents have not been revised, and are up to date. Document collection should not be required for policies and procedures that have not changed.
- Extend the time between scheduled audits for hospitals with successful audits and satisfactory processes.
- Allow hospitals to produce state board of pharmacy examination results as documentation of compliance with state pharmacy laws.

Suggestions for improving the IPAP process:

- Provide member hospitals with regular updates of drugs added or deleted from an IPAP.
- Eliminate the requirement that an insurance investigation be performed at the time of each refill and substitute annual updates.
- Deliver drugs only to the pharmacy or the attending physician as a means to effectively track drug disbursements as opposed to delivering drugs directly to a patient.
- Accept email or on-line submissions of documentation related to applications, renewals and audits.
- Standardize federal poverty level (FPL) eligibility requirements.

The SNHPA committee recognized the fact that all of the responsibilities cannot be the burden of drug manufacturers and as such presented what I found as one of their most

compelling suggestions. The committee would develop a set of best practices, covering key criteria for managing an IPAP which would in turn be high risk areas in an audit. Once suggested policies have been established, member hospitals would be able to adopt the appropriate documents and implement processes that are both compliant and efficient.

“We sent [the vendor] a document in an effort to start a dialogue.” said Rita. “With the tough economic climate and growing numbers of uninsured patients, we are anxious to start a dialogue with the drug manufacturers so our member hospitals can maximize the use of IPAPs.” The vendor responded by saying that they are reviewing the concerns and suggestions with drug manufacturers, but that no immediate response from the manufacturers should be expected due to the complicated process for business rules.

While CIS would agree that change cannot be expected overnight, we would suggest that the fact that the committee is willing to proactively address their concerns by establishing standardized policies is the best place to begin the process. Multiple drug manufacturers are involved in IPAPs; however, the common denominator of SNHPA membership and a single vendor handling most of the IPAP compliance audits provide a head start in implementation. From the perspective of CIS’ auditors, such standardization would allow for the audit process to be more efficient, allowing more time for transactional testing of patient records and dispensing activities that are so crucial to IPAP audits.

As the SNHPA advisory committee moves forward with any initiatives, they welcome feedback and suggestions from drug manufacturers. Manufacturer representatives can contact Rita Baskett at 202-552-5857 or rita.baskett@snhpa.org with comments or questions.

¹ Release 78: Medicaid Drug Rebate Program, Centers of Medicare & Medicaid Services

² Release 78: Medicaid Drug Rebate Program, Centers of Medicare & Medicaid Services