A Proposal for Universal Form for PAP and PAP Audit

Social needs are not inelastic. In our society, needs related to health care are growing and health care resources are not keeping pace. In this time of health care reform, economic volatility and uncertainty, present conditions and future changes promise that more people will be in need.

Patient Assistance Programs, also known as PAP, provide $3-4 billion in medication each year. PAP is intended to help meet long-term medication needs of the poor. Participating pharmaceutical companies provide at least a three-month supply of free medication to qualified individuals.

There are two ways to access PAP. First, there are IPAP or Institutional Patient Assistance Programs. They constitute 5-10% of the overall PAP market and provide bulk medication to clinics able to comply with pharmaceutical companies' safety, security, and patient eligibility requirements. Each pharmaceutical company then audits sites to determine if requirements are complied with, and audits some portion of PAP patient records. In this way, pharmaceutical companies are reassured that medications are only given to those that could not otherwise obtain them.

The other kind of PAP, "traditional" PAP, comprises the vast majority of the pharmaceutical companies' domestic charity programs and is conducted through small and independent practices, clinics or individual clinicians' offices. For each drug sought, a separate form must be completed. This process is very time consuming on the front end in terms of time spent completing the applications. In addition, there are superimposed inventory costs and mailing fees associated with each drug and each patient, as well as with any program renewals. In contrast to IPAP, where the pharmaceutical companies spend significant resources on auditing on the backend, traditional PAP demands resources on the front end to enter the forms into a database and to verify the information submitted to qualify the patient for the program. It has been estimated that that it costs the pharmaceutical companies $15-$70 for each drug application.

The demographic information on the different PAP forms is identical for over 90% of the questions. There is some variance in eligibility criteria and the language of information release statements. The rationale for this cumbersome methodology is likely driven by the proprietary nature of each pharmaceutical company's information. Concerned parties have bandied around the idea of creating a universal application form to generate better efficiencies and improve access. Efforts to date have focused on the creation of one form, where participating companies would agree upon a universal set of questions concerning demographics, information gathering and exchange, and ideally, common agreement on eligibility criteria. Consensus around these parameters, however, has historically proved too difficult. In addition to fear of losing confidential business information, other obstacles in the labyrinth to develop a universal application form have been identified as fear of violating HIPAA, and antitrust concerns.

With the advent of new technology (cloud, etc.) and its inherent capabilities, "universal" form can now be seen as tangible. With the ability to isolate and secure individual data, a universal form can be developed allowing for each individual company's data set to remain proprietary and accessible in a secure manner.

What is required and is available is a digital system that both improve efficiencies while at the same time simplifies data entry, eligibility, and clinical interaction. This requires a system that is trusted by all, is secure, protects privacy, and ensures that companies can only obtain the information they are authorized to access. Such technology would allow competitors to come together to create or share in a mutually beneficial endeavor for them and those who are served by PAP.

Various health information exchanges allow traditionally competing organizations to access data from care delivered in other organizations in ways that improve patient care while not diminishing competitive strategies different delivery organizations pursue. At the level of integrated delivery networks and accountable care organizations, strong governance has allowed multiple health care plans to use the Geisinger Health System's technology infrastructure without fear of "patient or information cannibalization." Costs are lowered for everyone; care is improved for everyone.

Across the United States, both privately funded and federally funded health information exchange organizations allow for traditional competitors to obtain patient consent and to share clinical information to advance patient care. Memphis, Tennessee, for example, has a coalition of every major hospital that makes information available for clinical care across the region. That coalition has strict governance, consent, and auditing policies, which preclude use of information for inappropriate gain. At the national level, the merger of

SureScripts and RxHub into the new SureScripts, LLC brought together pharmacy benefits managers, independent pharmacies, and chain drug stores. In this circumstance, as well, traditional competitors combined resources for their mutual benefit and to advance a greater societal good. These examples are models for a path forward.

The system envisioned would be used initially for the many clinicians who rely on pharmaceutical patient assistance programs to provide care. The introduction of a one-stop shopping portal would allow clinicians to enter demographic data one time, identify if the patient is already in the database and, if not, to add an eligibility request. Since each patient may require different drugs and the majority of questions on the forms are common, the web interface could be designed to add only required fields depending on the fields previously submitted.

From the pharmaceutical companies' perspective, each sponsor would be able to receive requests and analyze reports only for those products they sponsor. The system can be designed to make other access impossible. Should a common need arise, via a governance mechanism built in to the system design, reports across a range of issues could be easily generated.

In each case, a number of technical and organizational principles ensure the economies and expectations of concerned parties. These include:

Contracts. Parties engage in contractual relationships that define their rights, responsibilities, and penalties if terms are violated. These contracts focus primarily on data use, privacy, and other concerns that generally, are more restrictive than federal HIPAA rules.

Governance and oversight. Participating entities, that create and use the universal form, will form a governance structure that will also be charged with refining and guiding the evolution of this innovation.

Strong security infrastructure. The data infrastructure must be secure at every step from authenticating identity to authorizing access and use. These data will likely be seen as personal health information and, therefore, subject to HIPAA regulation.

Audits. The system must be trusted. Auditing through a third party, selected by the governance entity, is essential to ensure that the contracts are being enforced and that the users understand the implications of violations.

Low cost. The system must be far less expensive than the status quo. The true cost of the status quo is hard to calculate because costs are distributed across so many individuals and firms. In addition, the program's value cannot simply be measured in monetary terms. The true cost of the program can only be determined when taking into account the benefits that its implementation will have. These benefits include the minimization of the time and labor required to conduct PAP and the gains achieved by improving access to medications to those that qualify and the subsequent improvement in their quality of health. Weighed against the costs of empowering this program will also be the cost savings appreciated by those (e.g. emergency rooms and hospitals) downstream from the rushing torrent of escalating health care costs.

Benefits. Every organization that invests in this endeavor must realize a gain.

At its heart, the system consists of:

A team of individuals administering the resource
Means by which web based forms are generated
A secure database to store data
Strong authentication and authorization processes (technology and people)
A detailed audit log
Patient/record matching algorithms
Queries that allow appropriate reporting but do not allow one company to view aggregate data concerning other sponsors' contributions. (Some form of overall usage may be required for financial support of the resource, but a confidential third party could do this inexpensively.)

Change can come in two forms - either incrementally or in radical, quantum steps.
To allay concerns of having to incorporate sweeping change, we envision that the universal application form could be piloted in a small subset of indigent clinics, those already operational that have a proven track record with PAP and/or IPAP. A small group of pharmaceutical companies will be solicited to participate in the pilot as well. Pilots could be conducted through regional or state health information organizations conducting health information exchange, integrated delivery networks supporting exchange of data, or the rapidly evolving commercial sector. Once the concept is successfully tested and revisions made, the hope would be to expand the program nationally. Expansion would be controlled, as only a limited number of clinics would ultimately have the infrastructure and capacity noted above.

The template for this universal form should also be applicable to the parallel development of a universal audit form or methodology for the clinics and pharmaceutical companies that participate in patient assistance programs and/or IPAP.

It is possible that such a system could be used as a de-facto audit for larger institutional clients (IPAP), as well. Clinicians, and their support staff in these systems, could be encouraged to complete the forms when they see their patients – a task, as described above, requiring little time after initial registration. At some future date, interoperability among systems could allow more direct input, but such a possibility should not be a priority given the current state of electronic health records (EHR) interoperability and the many competing areas of attention EHR maintenance provides.

The costs of the infrastructure needed to support a universal application form might be an obstacle and prove challenging. However, it is more likely that the costs might be reasonable and affordable given the government mandate that the health care industry move to greater electronic storage and exchange of information. Systems are in place or are aggressively being designed that can address and satisfy all of the concerns listed above. As this approach is developed, the "buy vs. build" question should be raised at every step.

The value proposition for the universal application form can be seen from many different perspectives. For the patient, it would improve their health by simplifying the pathways and time course required to procure charitable medication. Web portals could allow pharmaceutical companies to receive appropriate recognition for their charitable activities. For the clinics, providers, and staff that comprise the network that serves the poor, a universal form would not only improve medication access to a given individual but its efficiency could potentially reach hundreds to thousands of clinics across the country and millions of patients that they serve.

In this uncertain time, pharmaceutical companies may be hesitant to change existing operating procedures and adopt new ways to give their medication philanthropy. Yet, if the past can help to predict the future, pharmaceutical companies will continue to be the major providers of medication to the less fortunate, regardless of the economy. As the pharmaceutical companies' largesse amounts to billions, they will hopefully welcome innovation that creates better efficiency and saves them money along the way to fulfilling their humanitarian missions and inherent corporate social responsibility to improve the health of all.