Discussion Questions

)escribe the authorizing environment for folic acid fortification in the Jnited States.

Why would a decision based on strong British studies influence the U.S. lecision to fortify cereal products but yield a delayed response in the J.K.?

Contrast and compare the variables and their values used in the before ınd after CBA studies. What conclusions would you draw from them ıbout that approach in this case? In general?

Chapter 13

Implementation Strategy and Planning

Health care delivery, like politics, is mostly local. No matter how good the policy analysis process, the policy selected as a result of that process will fail unless it elicits the support of its local implementers. Health-related activities exhibit deeply contrasting tendencies: health care processes are slow to change in some areas, yet the pace of change is rapid in other areas. Some argue that the adoption of new technologies is driving up costs, whereas others argue that failure to adopt new technology is partly responsible for escalating costs. Christensen, Bohmer, and Kenagy (2000) used the health care industry as an example of the need for disruptive technology to come in and overcome inertia. Their model applies very well in some areas, such as health information technology, but not in others, such as noninvasive surgery.

Dopson and Fitzgerald (2005) edited a book about the "implementation gap" for evidence-based health care in Britain's National Health Service, where centralization of management and financing would seem to create a more fertile environment for change. In a chapter contributed by Dopson and his colleagues (Dopson et al., 2005), the authors pointed out that failure to achieve goals that had been carefully planned has a long history in public policy analysis. Implementation failures could be explained as political bargaining as usual at a micro level; however, empirical studies suggest

that implementation is a separate stage of the change process (Torenvlied & Thomson, 2003).

The policy process must consider how to implement a policy decision and how to promote that implementation. The Australian government considers implementation so important that it established a Cabinet Implementation Unit in late 2003 within the Department of the Prime Minister and Cabinet.

The White House might want to consider a similar unit after the Obama administration's experience with the 2013–2014 rollout of the Web-based insurance exchanges. One can make a substantial list of the basic requirements of effective program implementation that were violated in that process.

LEVELS OF IMPLEMENTATION FAILURE

There can be many reasons for a policy to be adopted but not implemented. Sometimes plans are unrealistic. Sometimes there is a failure to execute critical elements of a plan, whereas other plans are foiled by much more subtle (all too human) resistance. Still others are simply overtaken by events—wars, budget crises, changes of government, competing technologies, or differing ideologies. Many social programs started at the federal level with great effort and then failed in the field over time. McLaughlin (1984), noting how often legislators develop and adopt social programs that miss their intended objectives, observed:

> It is sometimes tragicomic to read the laws of entitlement, such as the one guaranteeing equality of education for the handicapped and exceptional children, and then see how they work out in group homes, classrooms and clinics. Some have blamed public parsimony. Others would cite professional narrowness, individual insensitivity, and bureaucratic myopia. But much of the blame falls on the haste with which public policy is adopted, implemented, and then displaced by new policy. (p. 83)

The "deinstitutionalization" effort of the 1970s is a good example of failure to execute. After early antipsychotic drugs became available, the inpatient populations of psychiatric hospitals began to decline. Community mental health centers created to serve people released from mental institutions were up and running in many areas. Medicaid and Medicare provided some funding, but despite promises to transfer budgetary resources that had previously gone into psychiatric hospitals to these centers and other community organizations, the funding never arrived in sufficient amounts

to provide both direct care and supportive services such as housing and employment training. An entire new population of homeless individuals appeared in our cities, and the terms *revolving door* and *bag lady* entered the public vocabulary. Hospitals and community centers did not provide coordinated care; they were often separate systems that competed for the same resources. Furthermore, many community mental health centers drifted away from the goal of supporting deinstitutionalization of the mentally ill and began serving a much broader spectrum of patients. As Torrey (1997) noted, "Once trained, however, the vast majority of these professionals decide to provide psychotherapy for people with mental health problems rather than treat people who were mentally ill" (p. 185). It is not easy to keep well-intentioned policies from going off the tracks. As the saying goes, "The devil is in the details."

IMPLEMENTATION PLANNING

Implementation planning arrives early and stays late. It is important to involve all stakeholders, including the implementers. An Australian Cabinet Implementation Unit process guide referred to two implementation processes: (1) implementation assessment, which contributes to the documentation that accompanies the submission of a proposal to the cabinet, and (2) implementation planning, which continues that process in much greater detail once the decision is final. **Figure 13-1** outlines the stages of the Australian cabinet's implementation planning process. Several topics discussed below—scope, funding, risk management, and schedule (which is discussed as part of the work breakdown)—may also be inputs, alongside program objectives, outcomes, and governance considerations connected to the strategic decision-making process.

Scope

Policy making is an art, and the "who, what, where, when, and how" may be changed either subtly or substantially. Implementers must be aware of what was actually approved. There is a saying that the camel was intended to be a horse, but it was designed by a committee. Note the result: the camel is highly adapted to its environment, but it is something quite different from a horse. Consequently, it needs a very different management approach to operate it and evaluate its ultimate performance.

In the latter stages of implementation, it is important to establish lines of authority and accountability for implementation and to consider how the effort interacts with other initiatives and programs already under way.

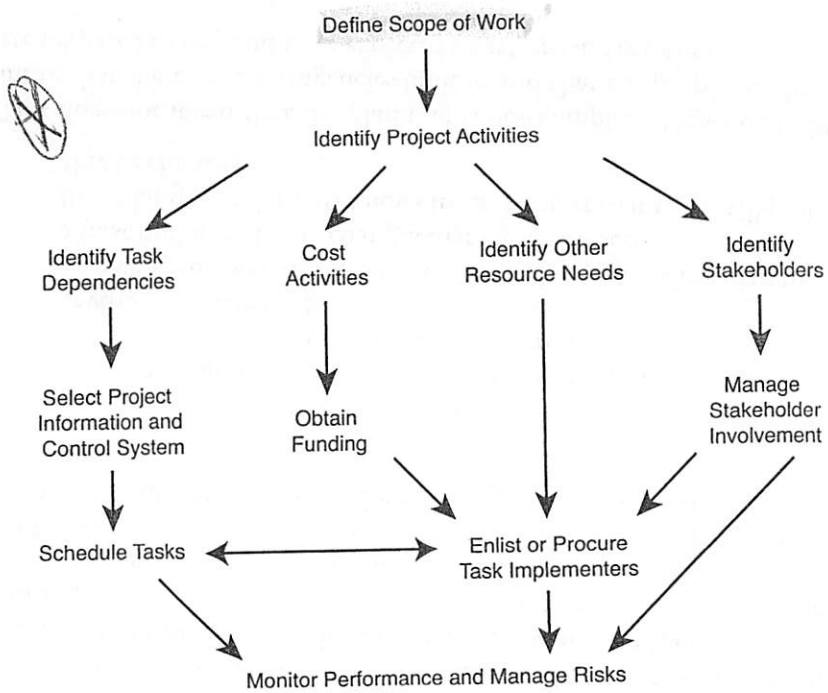

Figure 13-1 Stages of implementation planning.

It is also important to consider whether the new policy can be implemented effectively using existing organizational structures, management systems, and funding approaches or whether there is a need to establish a new structure designed to deliver the changed output.

Work Breakdown

This stage is a detailed analysis of the tasks generated by the implementation requirements of the policy. Political decision makers are likely to establish important dates (milestones) for implementation, dates that may or may not be achievable. Then the implementing organization must get to work:

- Identifying the tasks to be performed, such as submitting a detailed budget, hiring personnel, finding office space, issuing rules and regulations, establishing advisory committees, and specifying reporting requirements

- Identifying the units and individuals responsible for each task and gaining their commitment to complete the task within a specific time period
- Establishing reporting responsibilities for the status of each task
- Including coordination tasks as well as intradepartmental tasks
- Developing a master schedule and an estimated time of completion for the project along with mechanisms for monitoring progress

Depending on the complexity and urgency of the project, the project implementation staff may choose to use any one of a number of project management techniques and their associated software to show what the resulting project duration will be and whether the original target is likely to be met. If not, implementation planners may decide to undertake a number of efforts to "crash" the project in order to remain on schedule.[1] This process works best when the estimate of how long an activity will take comes from the individual or team that will be responsible for that activity. This encourages participants to make realistic estimates and then commit to meeting their own estimates. For example, the Obama administration shortened the testing period for the insurance exchanges and failed to have top-level oversight of the process to determine whether this mission-critical system was up to its assigned tasks.

Funding

Few proposals get considered without a cost figure attached; however, additional steps related to funding may need to be taken once that figure is approved. Congress authorizes many more initiatives than it funds. For example, in 1998, Congress passed and President Clinton signed the Ricky Ray Hemophilia Relief Act, which authorized a compassionate payment of $100,000 to each hemophiliac infected between 1982 and 1987 from contaminated blood products, or to their families if they had died. This was to compensate for lax government control of the blood supply. The authorization bill did not include the funding required, estimated to be $750 million. Only after considerable effort by advocacy groups was $75 million appropriated in fiscal year 2000, $100 million in fiscal year 2002, and $475 million in other years. By the time the program was terminated in 2005, $559 million had been dispersed.

[1]Many systems for project planning and scheduling are available, including the Critical Path Method (CPM) and the Program Evaluation and Review Technique (PERT). These methods enable staff to build a feasible schedule and to track performance, updating that schedule as the effort moves along. Microsoft Project is one such program that is usually readily available.

Risk Management

The Australian *Guide to Preparing Implementation Plans* states the following:

> By understanding the potential risks which may affect the implementation of a policy measure, agencies can reduce the likelihood or consequence of "unpleasant surprises" that may jeopardise the achievement of policy objectives." (Cabinet Implementation Unit, 2006, p. 23)

It suggests that likely risks include

- Unclear objectives and deliverables
- Unrealistic schedules
- Shortages of key resources—funds, people, equipment
- Lack of infrastructure and supports
- Lack of agency internal capacity

Whatever the risk, the planning process needs to assess the likelihood that it will occur, its severity and impact, how to mitigate it, and who is responsible for preventive measures. It also needs to address monitoring and how to initiate any needed actions. In situations of high uncertainty and high impact, such as national security intelligence, analysts are now required to report their estimates of their certainty regarding their findings.

One way for implementers to ensure that they will be able to respond to changing conditions is to keep the planning flexible. How does a plan stay flexible?

- By not getting too detailed too early
- By not planning to use the available resources up to their limit
- By checking in with all implementers from time to time to see if anything has changed
- By having the periodic reviews to allow other parts of the plan to adjust to the "as built" changes that naturally occur
- By making sure the staff knows from the start that there will probably be changes

This does not mean that the planning is not complete. However, it does mean that there are contingencies built in and that the people on the job are prepared to respond to unexpected situations as they arise.

Stakeholder Engagement

Implementation must include a review of the stakeholders, including the following:

- Who needs to be kept informed?
- Who needs to participate in what detailed planning activities?
- Who can be an opinion leader or champion of the program?
- Who needs further training and motivation?
- Who can be an enabler?
- Who can be a blocker and needs to be co-opted?

Then, as **Table 13-1** illustrates, implementation planners must identify the type of commitment needed from the implementation stakeholder, how to secure it, key messages that need to be delivered, and who is responsible for the relationship. Decisions about how to deliver the message and maintain the relationship follow. Should it be delivered personally, by email, through the media, through a representative, and so on? After those coordination and communication tasks are identified, they can be scheduled and assigned to someone.

It often is best to approach this work with stakeholders as meaningful consultation and collaboration. This can make initial implementation easier because stakeholders who feel that their ideas have been considered and their concerns addressed are less likely to try to subvert the process. Chances of success over time are greater if the people and organizations affected by the project recognize its value and are invested in its success. There will be times, though, when an implementing agency is given a mandate to implement a policy change on a specific timeline over the objections of important stakeholders, and this may force the implementation planners to develop a policy for "stakeholder management"—a term that is in disfavor but may be apt in such circumstances.

You may recall from discussions of evaluating political feasibility that most techniques involve collecting information from stakeholders. That

Table 13-1 Communications Strategy Tool

Key Stakeholder	Desired Commitment and Strategy for Securing Commitment	Key Messages That Need to Be Delivered	Responsible Officer

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is why the most popular framework for determining political feasibility is called "stakeholder analysis." Political feasibility inquiries can yield a lot of information that can be very important during the implementation process. If Delphi processes, key informant interviews, or other stakeholder outreach efforts were part of a feasibility evaluation prior to policy adoption, then implementers should review that material. Even if they feel they know the material, it could be helpful to turn to it with a fresh eye. A stakeholder concern that was not enough to prevent a policy's adoption, for example, could frustrate or even derail that same policy's implementation. Implementers might also consider employing such processes after the fact as part of their stakeholder engagement practices.

Resources, Including Sourcing and Procurement

Key resource needs should have been identified by this point in time because the funding requirements depend on the resources needed, especially personnel, equipment, and support systems. There may also be other less tangible resources that are mission critical, such as office space, computers and communication equipment, loaned personnel, and contractor personnel with special skills. For example, it is a frequent practice for contractors to assign their most competent personnel to preparing and marketing the proposal, but then substitute underutilized, less experienced, less skilled, or less costly personnel when the work gets under way. Implementation managers must stay alert to get the quality people and services that they expected originally.

Quality Assurance

The policy proposal usually specifies the quality and quantity of outcomes anticipated, and it may refer to the process and outcome measures to be used; however, implementation planners may still have to develop, validate, and install measures and measurement systems to monitor progress and suggest improvements as the implementation proceeds. When planning quality assurance measures, analysts should keep in mind the kinds of data, information, and documentation needed to conduct an evaluation after the policy has been implemented.

When it comes to sequencing these implementation activities, there is no magic order. After the proposal stage, many activities may have to go forward on parallel tracks, with the implementation team making adjustments as problems and opportunities are encountered. New technology or results from ongoing studies may lead to program changes after the

policy makers have completed their work. If so, the implementation team should inform the policy makers of the change so that there will be no big surprises when the effort is being reviewed (e.g., during a site visit). The list of implementation activities is often quite detailed, and it is up to the implementation team to decide how much planning time to invest in each activity. The systems necessary to plan and monitor some of these stages may be in place already. The budgeting and scheduling functions should be basic management activities everywhere.

SETTING UP TO SUCCEED

Ample evidence suggests that implementation is enhanced by involving implementers early. This builds their commitment to the plan. Health care is going through a transition from a professional model that emphasizes individual responsibility, autonomy, and accountability toward an organizational one, hopefully one where organizational learning and transformation are norms. To succeed at implementation in this contentious environment, a number of things need to happen, including:

1. **Shared responsibility is accepted.** Team leaders and members at all professional levels must come to share overall responsibility while still accepting individual responsibility for assigned tasks. The industrialization of health care often means that treatment processes are carried out by multiple actors whose actions must be coordinated.
2. **Leadership takes place at multiple levels.** The team involved in developing a policy must have facts about how the system works at the operational level as well as the strategic level. Many developing countries still suffer from the system developed by the British Colonial Office for managing the Empire. This consisted of mostly locals organized into two cadres: one, the civil service, developed policy, whereas the other, the health service, for example, implemented it. A small group of British officials controlled the flow of information from one to the other. The policy makers produced brilliant analyses that circulated in files held together with red ribbon (called *red tape* by the English), but these analyses often proved unworkable for implementers in the field. It was an efficient way to use a small expatriate staff, but it did not necessarily produce effective delivery systems. All too many policies and plans have become "shelf art," sitting there unused because implementers do not see them as practical or relevant.

THE ORIGIN OF A POLICY

The labor, delivery, recovery, and postpartum nursing team at a community hospital was reviewing its procedures and cost items in order to become more competitive in their city. One policy that puzzled team members was sending 100% of the placentas to the pathology laboratory after delivery. They kept asking around for the source of that rule and found that it stemmed from an incident many years earlier. At the time, the daughter of the chief of obstetrics was having a difficult delivery and encountered a problem that might have been handled more effectively if the placenta from her delivery had been saved and analyzed. The angry chief thoroughly chewed out the OB nursing staff for not saving it. To avoid such a confrontation in the future, the nursing supervisor instituted the rule that all placentas would go to pathology. Both the chief of obstetrics and the nursing supervisor had long since retired, but the rule lived on. The three obstetricians currently practicing at the hospital developed a set of criteria for sending placentas to the laboratory. This new rule decreased the number of pathology reviews of placentas by 95%, resulting in substantial cost savings to the patients and the hospital.

3. **People understand the core business and technical processes, values, and mission of the organization.** Participants must be knowledgeable and consistent in their decision making about policies and implementation. Policies and processes rarely bolt out of control. More typically, they silently drift away from the optimal as individuals and groups make incremental local adjustments in response to local events, stimuli, and experiences. The example in the box on pathology review of placentas illustrates how one process moved away from its appropriate levels.
4. **Expectations are managed.** Some participants will be optimistic and expect too much, whereas others will be pessimistic or cynical and expect too little. Wilson and McLaughlin (1984) suggested that one needs to work out a psychological contract with the planning participants, one that recognizes the scarcity of resources and directly addresses the WIIFM (what's in it for me?) question. **Table 13-2** outlines some of the factors such a psychological contract might consider. In essence, the contract would specify what each party gets from the exchange beyond monetary considerations.

Table 13-2 The Psychological Contract

The Employee Gets
Performance standards that represent realistic trade-offs between funds, personnel, schedules, and service levels
Personal courtesy and respect
A supportive environment
Meaningful and purposeful work
Reasonable conflict and tension levels, mediated by clear standards for priority setting and evaluation of work
Opportunities for personal development
Profession and organizational recognition for good work
Security, as long as funds are available
Process for psychological contract change processes that reflect changing resource conditions
Scarce resources
The Organization Gets
An honest day's work, at least
Loyalty to the organization
Initiative, especially in resource use
Job effectiveness and efficiency in meeting overall organizational goals
Flexibility and willingness to wear multiple hats under tight staffing
Acceptance of reasonable trade-offs among professional norms and organizational needs
Participation in psychological contract change processes that reflect changing resource conditions

Source: Reproduced from: Wilson, M., & C. P. McLaughlin. (1984). *Leadership and Management in Academic Medicine*, p. 310. Josey-Bass.

5. **Planning is continuous.** The health care environment is continuously changing. There are many more opportunities and challenges than most organizations can take on at any one time. Through functional and cross-functional teams, managers involve providers and others in setting priorities, developing and evaluating alternatives, and meeting the many new challenges.
6. **Orientations are prospective rather than retrospective.** Dopson and Fitzgerald (2005) and Senge and colleagues (1994) observed that behaviors and beliefs take time to change and require both abstract reasoning and experiential reinforcement. It is often easier to do things the way they have always been done. Looking to the past

for precedent is usually a rational step in assessing a situation, but there is little assurance that what an organization has been doing is effective or will be so in the future. "Transformational leadership continually brings forward the vision of the future organization and indicates how the organization can get from where it is in the present to where it wants to be in the future" (Upshaw, Steffen, & McLaughlin, 2013, pp. 293–294).

7. **Performance is assessed and rewarded.** Effective policy change requires that the organization be prepared to commit real resources and provide support mechanisms for recognizing creativity and innovation. Personnel evaluation processes and procedures must be in place to encourage implementers, as well as policy makers, to seek new ways to get things done and to prepare for the changing future.

THAT ALL-IMPORTANT START

Starting right is critical. If a team is involved, especially a multidisciplinary one (which would be the case for just about anything clinical), plan to offer leadership throughout the team formation cycle, which usually progresses through the following four stages:

1. Forming
2. Storming
3. Norming
4. Performing

Forming

The team needs to understand fully the factors behind the policy change and how it links to the institution's strategies. The team's initial efforts should be well supported and include tasks that are carefully chosen to build a shared experience of success. At this stage, the team must also consider whether it includes representation of all the important implementers.

Storming

Because health care settings are complex and have many built-in tensions, team members often start out blaming, finding fault, or expressing distrust of others. The team members have to be kept focused on their task until they begin to understand it and accept each other's viewpoints.

Norming

The group can then set up norms of operation, detailing, for example, how decisions are made and how work is allocated. Do we vote? Do we have to have a consensus? What do we have to clear with higher authority? Do some professional groups have veto power?

Performing

After the barriers at each of the preceding stages are dealt with, the team can get on with its assigned tasks effectively or, having addressed them and failed to get over them, seek further guidance or facilitation.

PROVIDING FOR PERIODIC REVIEWS

Major change projects often require that multiple teams go forward in parallel. Again, one or more of these may veer off on its own path, so it is important to stage periodic review sessions in which each team reports what it is doing, compares its progress against measures such as budget and schedule, and shares what implementation barriers it is experiencing. This process enables management to assess overall progress and make adjustments to the current plan where necessary. It also allows individual team leaders to see where they need to interface with other teams in order to meet their objectives and how to adjust their efforts to reflect what they learn at the review. The larger and more complex the project, the more important these periodic reviews become.

IMPLEMENTING POLICIES THAT AFFECT CLINICAL OPERATIONS

One of the more problematic areas for implementing policy involves getting professionals to change the way they carry out professional tasks. This has been a topic of concern to those who study quality of care, provide continuing professional education, or sell pharmaceuticals and other supplies to the health industry. The move toward greater use of evidence-based medicine is a case in point. For example, Dopson and Fitzgerald (2005) provided a meta-analysis of a number of studies of implementing evidence-based practices in the U.K. Health Service, in which the concluding summary by Ferlie (2005) emphasized the role of leadership, organizational support, and the differences between *knowledge* (i.e., information) and *practice*:

> In the best case examples, there appeared to be a circular relationship between research evidence and experience—they reinforced each other and were woven together. At other times, there was a tension between craft knowledge and formal evidence. It should be remembered that clinical practice contains an element of judgment and tacit knowledge more reminiscent of craft skills than traditional conceptions of science. It may be unwise to force a stark choice between the two modes (experience or science), but there may be a need to balance both. (Ferlie, 2005, p. 188)

Paul Batalden at Dartmouth has suggested that professional training include a microsystem approach to continuous improvement in health care, operating alongside issues- and organization-centered efforts. Mohr and Batalden (2006) identified eight dimensions of an effective, improvement-oriented microsystem (a teaching clinic or hospital service):

1. Constancy of purpose
2. Investment in improvement
3. Alignment of role and training for efficiency and staff satisfaction
4. Interdependence of the care team to meet patient needs
5. Integration of information and technology into work flows
6. Ongoing measurement of outcomes
7. Support from the larger organization
8. Connection to the community to enhance care delivery and extend influence

THE POSTMORTEM

Assuming that the group doing the analysis and planning will do this kind of thing again, it is critical to review the group's own performance. This postproject analysis should be done by the planning group if the project is small or medium-sized, or by an independent evaluator if it is large or mission critical. Evaluation should study two aspects of the project: process and outcome. Process analysis should take place relatively quickly after the final report is delivered and should ask this question: "If we had to do this analysis again, what would we do differently?" Because this can be threatening interpersonally, a little humor would not hurt. The list of phases of a project in **Table 13-3** can be used to lighten things up a little and may also point out opportunities for improvement.

Clearly, one has to avoid using the postmortem merely to assign blame and to make sure that the accolades and rewards go to all those who really contributed to the process.

Table 13-3 A Little Humor Might Help: Six Phases of a Project

1. Enthusiasm
2. Frustration
3. Panic
4. Assigning blame
5. Punishing the innocent
6. Rewarding the noncontributors

Source: Reproduced from: W. A. Fischer, personal communication. Used with permission.

Outcomes assessment has to wait until the outcomes are evident. It can only be justified for major policy proposals that were actually implemented; otherwise, a second analysis might be needed to focus on what might have been done differently to get that proposal implemented. The failure to implement might be primarily due to outside factors. Either way, one should be able to go back through the analysis and see how well the group defined the situation, assessed the technology, outlined the economics, adjusted to the political system, planned the implementation, and presented the product to the decision makers. Such a review is a key to improved organizational learning about policy analysis.

CONCLUSION

There is no silver bullet to make implementation easy; however, the elements of successful implementation are well known. They involve top management consideration and support. They require an understanding of the social context in which change takes place. Would-be implementers must focus on the players, their roles, their barriers to action, and the roles of leadership and influencers in bringing about change. From an academic viewpoint, all of these should be worked out so that strategic policies are not derailed by the implementation details; however, decision makers are usually not comfortable with that level of detail as they deal broadly with a wide range of issues. They are very uncomfortable with surprises after the fact, but they also do not want to be bogged down reading the fine print. That is just a managerial reality. Perhaps the best answer is to turn to the experienced presenters on the team who know the behavior patterns of key decision makers and ask for their assessment of the appropriate level of detail to present at each stage.

Case 13 340B Drug Pricing Program Oversight

Section 602 of the Veterans Health Care Act of 1992 was titled "Limitations on Prices of Drugs Purchased by Certain Clinics and Hospitals." It amended the Public Health Services Act by adding a new section, Section 340B, to that act. Section 602 of the Veterans Health Care Act read in part:

> Part D of title III of the Public Health Service Act is amended by adding the following subpart: "SUBPART VII – DRUG PRICING AGREEMENTS" LIMITATION ON PRICES OF DRUGS PURHASED BY COVERED ENTITIES "Sec. 340B (a) Requirements for Agreement with Secretary – "(1) In general. The Secretary shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid . . . to the manufacturer for covered drugs . . . does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding quarter, reduced by the rebate percentage described in paragraph (2). "Rebate percentage defined. – (A) In general. For a covered outpatient drug . . . the 'rebate percentage' is the amount equal to – "(i) the average total rebate required under Section 1927(c) of the Social Security Act . . . for a unit of the dosage form and strength involved during the preceding quarter divided by "(ii) the average manufacturer price for such a unit of the drug during such quarter. . . ."

Section 340B applied Medicaid drug discounts to drugs purchased for clinics that served many outpatients who were not eligible for Medicaid at qualified safety-net institutions. For the most part, eligible clinics were associated with hospitals receiving disproportionate share payments under Medicare, pediatric hospitals, and community health centers. Also included were specialized clinics and projects for HIV/AIDS, hemophilia, black lung, tuberculosis, and family planning, as well as those serving Native Americans and Native Hawaiians. Hospitals were required to be governmental or nonprofit with a contractual commitment to provide services supported by governments, have a disproportionate share percentage greater than 11.75, and not obtain the covered drugs through a group purchasing agreement. The drugs had to be used for patients of the covered entity and could not be resold.

A key provision of Section 340B read "(10) No prohibition on larger discount. Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1)." The Patient Protection and Affordable Care Act (ACA or PPACA) increased the 340B discount to 13% on generic drugs and 23.1% on branded drugs. Specific discounts have been reported to range from 15–60% on prescription drugs. The law prohibits getting both a state Medicaid rebate and a 340B discount on a drug.

BACKGROUND

In the 1980s, Congress established a discount drug purchasing program for the Veterans Administration. In 1990, it extended this discount program to Medicaid purchases on behalf of low-income and uninsured enrollees under the Medicaid Drug Rebate Program. Soon it became clear that this law conflicted with another requirement that state Medicaid programs receive discounts matching the lowest prices offered in non-Medicaid markets. Congress moved to remedy this problem. Otherwise, the participating pharmaceutical and biotechnology companies would choose to stop offering discounts across the board.

The 340B program is administered by the Office of Pharmacy Affairs within Health Resources and Services Administration (HRSA) of the Department of Health and Human Service. This office is tasked with auditing compliance with program requirements, especially the eligibility of covered entities, and program integrity concerning diversions and duplicate discounts and manufacturer pricing. However, this office has a very limited staff, and the number of institutions taking advantage of the program has been growing rapidly. HRSA also supports a number of other programs, such as the Ryan White HIV/AIDS program and community and rural health centers that are covered entities for 340B drug discounts.

The HRSA website describes the intent of 340B in a listing of Frequently Asked Questions to be "to permit covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" [HR Rep. No. 102-384 384(II) at 12 (1992)].

Although there are limitations on billings to Medicaid patients, there are no constraints on billings to non-Medicaid patients.

Case 13 *(continued)*

The ACA freed up hospitals to choose among discount sources such as 340B and their group purchasing organizations. The ACA also made a number of provisions to strengthen program integrity.

Section 1703 of the ACA called for a Government Accounting Office (GAO) study of the program:

> . . . that examines whether those individuals served by the covered entities under the program under section 340B of the Public Health Service Act (42 U.S.C. 256b) (referred to in this section as the "340B program") are receiving optimal health care services.
>
> (b) RECOMMENDATIONS. – The report under subsection (a) shall include recommendations on the following:
>
> (1) Whether the 340B program should be expanded since it is anticipated that the 47,000,000 individuals who are uninsured as of the date of enactment of this Act will have health care coverage once this Act is implemented.
> (2) Whether mandatory sales of certain products by the 340B program could hinder patients access to those therapies through any provider.
> (3) Whether income from the 340B program is being used by the covered entities under the program to further the program objectives.

THE 2011 GAO STUDY

That study was issued by the GAO in September 2011. In the conclusions it noted:

> The 340B program allows certain providers within the U.S. health care safety net to stretch federal resources to reach more eligible patients and provide more comprehensive services, and we found that the covered entities we interviewed reported using it for these purposes. However, HRSA's current approach to oversight does not ensure 340B program integrity, and raises concerns that may be exacerbated by changes within the program. According to HRSA, the agency largely relies on participants' self-policing to ensure compliance with program requirements, and has never conducted an audit of covered entities or drug manufacturers. As a result, HRSA may not know when participants are engaging in practices that are not in compliance. Furthermore, we found that HRSA has not always provided covered entities and drug manufacturers with guidance that includes the necessary specificity on how to comply with program requirements. There also is evidence to suggest that participants may be interpreting guidance in ways that are inconsistent with the agency's intent. Finally, participants have little incentive to comply with program requirements, because few have faced sanctions for noncompliance . . .
>
> PPACA [i.e., ACA] outlined a number of provisions that, if implemented, will help improve many of the 340B program integrity issues we identified. For example, PPACA requires HRSA to recertify eligibility for all covered entity types on an annual basis . . . Additionally, PPACA requires HRSA to develop a formal dispute resolution process, including procedures for covered entities to obtain information from manufacturers, and maintain a centralized list of 340B prices—provisions that would help ensure covered entities and manufacturers are better able to identify and resolve suspected violations. PPACA also requires HRSA to institute monetary penalties for covered entities and manufacturers, which gives program participants more incentive to comply with program requirements. Finally, PPACA requires HRSA to conduct more direct oversight of manufacturers, including conducting selective audits to ensure that they are charging covered entities the correct 340B price.
>
> However, we identified other program integrity issues that HRSA should also address. For example, the law does not require HRSA to audit covered entities or further specify the agency's definition of a 340B patient. While HRSA has developed new proposed guidance on this definition, it is uncertain when, or if, the guidance will be finalized.
>
> Because the discounts on 340B drugs can be substantial, it is important for HRSA to ensure that covered entities only purchase them for eligible patients both by issuing more specific guidance and by conducting audits of covered entities to prevent diversion. Additionally, while PPACA included a provision prohibiting manufacturers from discriminating against covered entities in the sale

Case 13 *(continued)*

of 340B drugs, HRSA does not plan to make any changes to or further specify its related nondiscrimination guidance.

Absent additional oversight by the agency, including more specific guidance, access challenges covered entities have faced when manufacturers' have restricted distribution of IVIG at 340B prices may continue and similar challenges could arise for other drugs in the future. (GAO, 2011, pp. 33–34)

HOW IS THE PATIENT HELPED?

The ACA and the GAO report said little about getting the resulting savings to the patient's bill. As the law has been modified over the years, the direct link to the low-income, uninsured patient has weakened. The discounted drugs can even be used for commercially insured patients. The 2011 GAO report found that "some covered entities passed 340B savings on to patients by providing lower-cost drugs to uninsured patients. For example, many covered entities determined the amount that a patient is required to pay based on the lower cost of 340B-priced drugs" (p. 17). The report noted that some covered entities had indicated that without the discounts they would have to close their pharmacy or curtail other services.

> For a number of reasons, operating the 340B program in the hospital environment creates more opportunities for drug diversion compared to other covered entity types. First, hospitals operate 340B pharmacies in settings where both inpatient and outpatient drugs are dispensed and must ensure that inpatients do not get 340B drugs. Second, hospitals tend to have more complex contracting arrangements and organizational structures than other entity types—340B drugs can be dispensed in multiple locations, including emergency rooms, on-site clinics, and off-site clinics. In light of this and given HRSA's nonspecific guidance on the definition of a 340B patient, broad interpretations of the guidance may be more likely in the hospital setting and diversion harder to detect. Third, hospitals dispense a comparatively larger volume of drugs than other entity types—while representing 27 percent of participating covered entities, according to HRSA, DSH hospitals alone represent about 75 percent of all 340B drug purchases. (GAO, 2011, p. 29)

OTHER IMPACTS OF THE ACA

The ACA added a number of classes of institutions, including affordable care organizations, freestanding cancer hospitals, clinical access hospitals, rural referral centers, and sole community hospitals. Many millions of uninsured individuals are to receive insurance. This would greatly increase the consumption of 340B drugs, even though one might argue that the original need for the 340B program was partially mitigated.

MANUFACTURER PUSHBACK

In early 2013, the Biotechnology Industry Organization (BIO) issued a white paper subtitled "A Review and Analysis of the 340B Program." It was cosponsored by the Community Oncology Alliance (COA), the National Community Pharmacists Association (NCPA), National Patient Advocate Foundation (NPAF), the Pharmaceutical Care Management Association (PCMA), and the Pharmaceutical Research and Manufacturers of America (PhRMA). The report's executive summary cited:

> Areas of most concern included the following:
>
> - Concerns that some uninsured, indigent patients may not be experiencing direct benefit from the program's existence.
> - Anecdotal evidence that clinical decision-making may be skewed by efforts to take advantage of the 340B discount.
> - Growing evidence of displacement of non-340B providers who serve a key role in providing patient access to important health care services. (BIO, 2013, p. 1)

The same executive summary cited the concerns expressed in the GAO report, as well as insufficient resources at HRSA to carry out its responsibilities under 340B and the ACA, the need for clearer guidance, and HRSA's use of "subregulatory" procedures to clarify definitions and establish interpretive guidelines.

The HRSA website contained the following observation:

Case 13 *(continued)*

PROGRAM GUIDELINES

> HRSA chose to publish guidelines in the *Federal Register* rather than regulations to administer the Section 340B program. Guidelines are the quickest and most flexible way to convey to all concerned parties how HRSA interprets the Section 340B requirements. Guidelines are also used to disseminate procedures that are acceptable under the statute. To ensure that the guidelines were as appropriate and responsive as possible to the legitimate concerns of the covered entities and manufacturers, comments were solicited on all of the guidelines before HRSA published them in a final notice.

The BIO white paper cited the changed guidance that allowed covered entities to use contract pharmacies as an example of HRSA expanding this program by administrative means. Subsequently, the number of 340B contract pharmacy arrangements climbed from about 3,000 in 2010 to more than 9,000 in 2012, with more than 12,000 projected for 2012. The white paper claimed these arrangements were forcing some community pharmacies out of business.

SENATOR GRASSLEY'S INQUIRIES

Senator Charles E. (Chuck) Grassley (R-Iowa) has often been critical of nonprofit hospitals, and his concern about their implementation of the 340B program is just one example. His office often follows up on public disclosures that provide an investigative opening and an opportunity to prod HRSA about its oversight of the program.

The UAB Inquiry

For example, as ranking member of the Senate Judiciary Committee, he sent a letter on May 19, 2012, to Dr. Carol Garrison, president of the University of Alabama (UAB) Hospital, stating that:

> The original intent of the program was to extend the Medicaid drug discount to the most vulnerable patients at PHS Clinics, those who are mostly, "medically uninsured, on marginal incomes, and have no other source to turn to for preventive and primary care services." . . .
>
> On February 16, 2011, Donna Evans, R.Ph., Senior Pharmacist, with University of Alabama (UAB) Hospital gave a presentation at the 340B Annual Conference in San Diego, California. In this presentation, Ms. Evans stated that the purpose of the Purchasing Committee is, among other things, to "maximize savings opportunities." Ms. Evan's presentation goes on to state that UAB Hospital tracks the top drug expenses for "possible change in admission[s] process." As an example of this change in admission process, Ms. Evans lists the drugs Melphalan and Busulfan and stated that the hospital "change[d] treatment protocol/location." Furthermore, Ms. Evans' presentation discussed the "discharge [of an IVIG patient] from [the] hospital to [a] Townhouse," for the purpose of maximizing savings opportunities associated with the 340B drug discount provided in an outpatient setting.
>
> Ms. Evans' presentation is deeply disconcerting (Grassley, 2012, pp.1-2).

Senator Grassley asked the hospital to document the frequency and economics of such changes in admission status and 340B discounts in general, what the hospital did with the savings, and whether HRSA had ever audited it.

The North Carolina Major Hospitals Inquiry

In 2012, McClatchy newspapers in Charlotte and Raleigh, North Carolina, ran articles about major hospitals buying up oncology practices and substantially raising chemotherapy drug prices in these outpatient settings (Alexander & Garloch, 2012). In September 2012, Senator Grassley sent letters to three major hospitals cited in the articles, asking how much they earned by participating in the 340B Program, the breakdown of the 340B payer mix, and how they had reinvested those 340B dollars into serving the most vulnerable patients. Senator Grassley summarized their replies in a March 27, 2013, letter to Dr. Mary K. Wakefield, HRSA administrator:

Case 13 *(continued)*

First, all three North Carolina hospitals provided a summary of revenue generated by participating in the 340B program from 2008. Below is a revenue summary . . .

Carolinas Medical Center	UNC	Duke
2008: $12,970,012	2009: $33,087,329	2009: $88,953,570
2009: $16,697,500	2010: $38,451,076	2010: $109,700,400
2010: $16,910,620	2011: $52,580,763	2011: $131,759,091
2011: $21,065,620	2012: $65,391,050	2012: $135,539,459

These are not small amounts.

. . .

These numbers paint a very stark picture of how hospitals are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread. (Grassley, 2013, pp. 1–2)

All three hospitals were able to provide their 340B payer mix for the period 2008–2010. The data for 2010 taken from Senator Grassley's letter is presented in the table below:

Hospital	Medicare	Medicaid	Self-pay	Commercial
UNC	23.1%	9.7%	12.0%	22.6%
Carolinas Medical Center	25.6%	18.3%	11.3%	41.9%
Duke	19%	8%	4%	68%

The *Raleigh News & Observer* of April 3, 2013, reported on Senator Grassley's inquiry and stated that "Last year, Duke University Hospital purchased $65.8 million in drugs through the program and received $135.5 million in revenue. Duke says it saved $48.3 million buying the drugs through the 340B program. That means the hospital made a profit of $69.7 million, instead of $21.4 million if it had not participated in the program"(Alexander, Neff, & Garloch, 2013, p. A1).

Sen. Grassley's letter then goes on to ask a series of questions seemingly aimed at getting HRSA to collect this type of data routinely.

Discussion Questions

1. What seems to be the true intent of the 340B drug discount program? How would you go about clarifying the legislative intent?
2. What conclusions do you draw from the data provided to Senator Grassley?
3. What data would you like to make the covered entities provide to HRSA on a routine basis?
4. Discuss the merits of using the "subregulatory" process versus the normal rule-making procedures.
5. As the ACA is implemented, what will be the impact of the 340B program on pharmaceutical and biotechnology firms?
6. What are the merits of using disproportionate share as a screen for whether acute care hospitals are covered entities? What about the average manufacturer's selling price as a denominator in calculating the discount? What alternatives would you recommend?
7. What are the merits of Senator Grassley's investigative methods, given that he holds formal hearings on health policy issues as well?
8. What events or policy shifts would support the contraction or expansion of the 340B program?