Chapter 7

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INTRODUCTION

Planning for extracorporeal shock wave lithotripsy (ESWL), whether done on the institutional, local, or regional level, may be affected by Federal policies in two ways. First, to the extent that institutional or local planning is driven by market concerns, it is affected by the Federal payment programs described in the previous chapter. Second, ESWL distribution and use may be affected by Federal health planning policies, which operate largely through State certificate-of-need (CON) laws and entail review and approval mechanisms. The Federal Government has been a strong proponent of regional health planning for much of the past decade, although interest has waned in the past few years,

The rationale for planning policies is that they may improve the distribution of major health facilities and equipment for which the market alone does not provide an acceptable solution. Under Medicare cost-based reimbursement for inpatient services, [1] it was hoped that planning policies would curb oversupply of hospital beds and expensive equipment. Hospitals under cost-based reimbursement had a financial incentive to acquire and use expensive technologies, with few countervailing influences. Requiring these facilities to get prior approval for capital expenditures was one potential way to prevent health facilities from acquiring more beds and expensive equipment than was necessary to ensure that sufficient services were available to the local populations.

The State CON programs that have been encouraged by Federal law have not met with unqualified success, In the past few years, representatives of the Federal Government, disillusioned with the inability of planning policies to curb high hospital costs and Medicare expenditures have emphasized payment policies as the mechanism through which to encourage providers to restrain hospital expenditures. But planning laws are still in place in most States, and planning as well as payment policies may have a strong effect on the adoption, diffusion, and distribution of ESWL. Government planning policies may also interact with the activities of providers—particularly hospitals and hospital chains, physician groups, and management companies—to lead to new ways of providing services that have major implications for the availability and distribution of ESWL.

This chapter examines the ways that federally stimulated-health planning policies, particularly the CON program, and other less centralized activities are affecting the distribution, cost, and availability of lithotripsy. It then describes the interaction of the formal planning system with the market-based planning activities and the implications of these new organizational arrangements for acquiring and providing ESWL, Finally, it discusses the effects of technological change, including advances in the use of ESWL, on the provision of this technology.

[1] Prior to October 1983, Medicare paid all hospitals on the basis of Medicare's share of the costs of the inpatient services provided in those hospitals, As costs rose, payments rose accc~rd i ngl}~,

FEDERAL PLANNING POLICY AND THE CON PROGRAMS

The Federal Government has been involved in health care planning for some time, an interest originally arising out of its substantial involvement in financing the expansion of health care facilities (6). Laws passed in the 1960s provided Federal funding to regional health planning agencies to support a variety of planning activities, including the review of projects being evaluated by the

fledgling State CON programs (6). The Social Security Amendments of 1972 (Public Law 92-603) extended Federal involvement in local and regional planning through the section 1122 provisions, which authorized the Federal Government to enter into voluntary agreements with States. Under these agreements, Medicare and Medicaid could withhold payment for their depreciation and interest shares of certain capital investments made by health care facilities if State or local health planning agencies did not approve those investments. (Section 1122 does not apply to operating costs.) However, due to limitations in authority and in financial support, these agencies were largely ineffective ***(6).***

Congress continued to express its resolve to encourage health planning with the National Health Planning and Resources Development Act of 1974 (Public Law ***93-641).*** This major planning legislation set up a consolidated system of local health systems agencies to plan, State planning agencies to regulate, and State coordinating councils to advise and link the two ***(6).*** It also established planning and development grants, and—most importantly—it required that States pass CON laws in order to receive future health-related funds from the Federal Government. [s]

The State CON Programs

CON laws, passed by the individual States, empower State planning agencies to deny reimbursement to hospitals for large capital expenditures unless the agency finds a "need" for the service to be provided. In order to comply with Federal regulations, States must have laws mandating CON review for certain new institutional health expenditures. These laws must include prior approval for all equipment purchases over $400,000 and all new institutional health services with operating costs over $250,000 per year **(42** U.S. C. ***300).*** States may have lower but not higher thresholds and remain in compliance with Federal law.

By 1983, all States but one (Louisiana) had CON laws. However, numerous problems have plagued the CON-based planning system since it was instituted in 1974. Observers have suggested that health planning agencies have neither the resources nor the incentives to fully enact their legislative powers (171), and early studies found little effect of CON on hospital investment (74). Also, Federal regulations do not require that new equipment acquired by physicians' offices be covered under CON laws, a deficit identified early in conjunction with the diffusion of computed tomograph$_y$(CT) scanners (175).

The extent to which CON laws are actually effective in reducing unnecessary services (and costs) is still an active subject of debate, and recent Federal funding for the CON-based planning program has stipulated that States not complying with the act not be penalized (179). Consequently, many States' laws are no longer in compliance with Federal thresholds, Table 14 presents the status of laws in each State as of April 1986. As of that time, 11 States had raised one or more of their CON thresholds above the Federal maximum levels, and eight States had no CON laws at all (158).

The Dornier lithotripter, with its cost of about $2 million, exceeds the equipment purchase threshold levels for CON approval in all of the States with CON laws. In many States, the addition of an ESWL unit may be considered a new institutional health service, rendering the unit subject to CON review on the basis of its high operating expenses as well. In 1984, potential ESWL providers in the States with CON laws generated a total of 94 applications for the purchase of extracorporeal lithotripters (78). In the first half of 1985, 175 CON applications for ESWL were received (39), and at least two States (Mississippi and Oklahoma) have developed specific guidelines for ESWL (193).

Because CON review for ESWL may be invoked either on the basis of purchase costs or operating costs, in theory CON laws could de-

[2] For the purposes of section 1122, "health care facilities" include hospitals, kidney disease treatment centers, skilled nursing facilities, intermediate care facilities, rehabilitation facilities, and ambulatory surgical facilities (42 CFR 100).

'Public Law 93-641 stated that if a State had not enacted a CON program by 1979, that State would not receive "any allotment, grant, loan, or loan guarantee, or . any contract, under this Act, the Community Mental Health Centers Act, or the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of *1970* for the development, expansion, or support of health resources in such State until such time as such an agreement is in effect. "

Table 14.–Certificate-of .Need Thresholds in Each State and the District of Columbia, 1986

State	Expenditure threshold requiring approval[a]			Require approval for some physician-owned equipment	Repeal or sunset date	1122 program
	Capital	New health services	Equipment			
Alabama	$ 600,000	$200,000	$ 200,000	no	none	no
Alaska	1,000,000	any expenditure	1,000,000	no	none	no
Arizona	—	—	—	—	March 1985	no
Arkansas	600,000	250,000	400,000	no	none	yes
California	1,000,000	certain services	1,000,000	no	January 1987	no
Colorado	2,000,000	1,000,000	1,000,000	yes	indefinite	no
Connecticut	714,000	any expenditure	400,000	yes	none	no
Delaware	150,000	any expenditure	150,000	no	none	yes
Dist. of Col.	600,000	250,000	400,000	yes	none	no
Florida	600,000	250,000	400,000	no	July 1987[b]	no
Georgia	600,000	any expenditure	400,000	no	none	yes
Hawaii	600,000	any expenditure	400,000	no	none	no
Idaho	—	—	—	—	June 1983	yes
Illinois	600,000	certain services	400,000	no	January 1986[b]	no
Indiana	750,000	0	750,000	no	June 1987	yes
Iowa	600,000	250,000	400,000	yes	none	yes
Kansas	—	—	—	—	July 1985	no
Kentucky	600,000	250,000	400,000	no	none	yes
Louisiana	—	—	—	—	Never enacted	yes
Maine	350,000	135,000	300,000	no	none	yes
Maryland	600,000	250,000	licensure	licensure	none	no
Massachusetts	600,000	250,000	400,000	no	none	no
Michigan	150,000	0	150,000	no	none	yes
Minnesota	—	—	—	—	June 1984	yes
Mississippi	600,000	150,000	400,000	no	July 1986	no
Missouri	600,000	250,000	400,000	yes	none	no
Montana	750,000	100,000	500,000	yes	July 1987	no
Nebraska	500,000	250,000	400,000	no	none	yes
Nevada	600,000	250,000	400,000	no	none	no
New Hampshire	600,000	250,000	400,000	yes	none	no
New Jersey	150,000	any expenditure	150,000	no	none	yes
New Mexico	—	—	—	—	June 1983	yes
New York	300,000	any expenditure	300,000	no	none	no
North Carolina	600,000	250,000	400,000	no	none	no
North Dakota	600,000	250,000	400,000	yes	none	no
Ohio	600,000	250,000	1,000,000	no	none	no
Oklahoma	600,000	250,000	400,000	no	1989b	yes
Oregon	variable	250,000	400,000	yes	none	no
Pennsylvania	600,000	250,000	400,000	no	none	no
Rhode Island	150,000	75,000	150,000	yes	none	no
South Carolina	600,000	250,000	400,000	no	none	no
South Dakota	600,000	250,000	400,000	no	none	no
Tennessee	1,000,000	any expenditure	1,000,000	no	June 1991[b]	no
Texas	—	—	—	—	September 1985	no
Utah	—	—	—	—	January 1985	no
Vermont	150,000	any expenditure	125,000	no	none	no
Virginia	600,000	any expenditure	400,000	yes	none	no
Washington	1,000,000	500,000	1,000,000	no	none	no
West Virginia	600,000	250,000	400,000	yes	none	yes
Wisconsin	600,000	250,000	600,000	yes	July 1989	no
Wyoming	714,000	150,000	400,000	yes	July 1989	no

[a]Many States have indexed capital and new health services expenditure thresholds to some measure of Inflation Most Stateswith Indexing use 1979 as the base Year and index according to increasesin the composite construction cost index Most States with a 1979 base year index now have capital expenditure thresholds of $736,250 and new health services thresholds of $306,750 (158).
[b]Only som,portions of the statute are scheduled to sunset

SOURCE J B Simpson, "Full Circle The Return of Certificate-of- Need Regulation of Health Facilities to State Control, " *Indiana* Law *Review* 19(4) forthcoming Summer 1986

lay or prevent many ESWL purchases in States that have such laws. However, if new, cheaper machines are approved for marketing, they may not require CON approval in States that exceed the Federal equipment threshold unless they are considered new health services.

Nearly all States with CON laws require review of new health facilities, including ambulatory surgical centers (158). However, ambulatory ESWL may be exempt from CON laws if a center offering only ESWL is not considered a surgical center under that State's laws. California, for example, requires CON review of ambulatory surgical centers ***(94),*** yet the first Dornier lithotripter in northern California was installed in a free-standing ambulatory center without undergoing CON approval for either the facility or the equipment ***(68).*** As demonstrated in table 14, only 15 States require licensure or CON review of equipment that may be used for persons who are not patients of a health care facility (158).

In States with weak or absent CON laws, it is possible that the section 1122 process, which allows Medicare and Medicaid to refuse to pay their share of the capital costs of major equipment whose purchase is not approved by a State agency, may again have some effect. Without a CON process, Medicare and Medicaid may choose to refuse to pay their share of the capital costs of ESWL for patients treated in unapproved facilities in those States that have a section 1122 agreement with the Federal Government. If this should occur, and if some facilities refused to treat Medicare and Medicaid patients as a result, these patients might be required to travel further for treatment. Those close facilities that consequently treat a smaller caseload might also have higher average costs as a result. At present, the section 1122 program is based on voluntary State participation, so it is likely to be a factor only in the four States with a section 1122 agreement but no CON program. However, if Congress does not pass legislation incorporating capital expenses into the Medicare prospective payment system, section 1122 participation will become effectively mandatory in every State (42 U. S. C., 1395).

The Effects of CON and State Health Planning Systems

CON laws appear to be influencing the growth of new arrangements for purchasing, sharing, and providing ESWL in two ways. First, they maybe encouraging the movement toward the provision of sophisticated services, such as ESWL, in ambulatory settings, Second, they appear to be encouraging, at least in a few States, the joint purchase of ESWL units by hospitals, physician groups, and management companies.

As they exist in most States, CON laws offer an incentive for health care providers to provide certain very expensive technologies out of the hospital altogether in order to avoid the time and expense (and possible rejection) of CON review. This incentive may have affected the service setting of both CT and MRI. Four years after their introduction into the United States, 18 percent of CT seamers were located in ambulatory facilities. Thirty-nine percent of MRI equipment were located in ambulatory facilities after an equivalent period of time (169). Free-standing imaging centers have emerged as an increasingly common phenomenon around the country **(64).** ESWL appears to be moving towards a similar diffusion pattern that will include an increasingly large number of free-standing ESWL centers as well as an emphasis on outpatient ESWL at many hospitals.

Shared purchase of major equipment among several hospitals or physicians has become a recently familiar theme in health care ***(96),*** and ESWL exemplifies a diverse array of such shared purchase arrangements. In Washington, DC, for example, three hospitals are copurchasing a lithotripter that is sited at one of the hospitals ***(60).*** In Cleveland, Ohio, two hospitals planned joint purchase of a lithotripter, sited in a separate facility, in order to share expenses and speed CON approval (56,113). In Memphis, Tennessee, six hospitals and a group of urologists have created a for-profit company to purchase a lithotripter that will be located at the University of Tennessee Medical Center if the project receives CON

approval (123). The ambulatory lithotripsy center in Los Gates, California, is jointly owned by several hospitals, urologists, and Uro-Tech Management Corp. ***(86).*** [4]In Dallas, Texas, several hospitals and urologists are planning joint establishment of a lithotripsy center for the International Biomedics lithotripter, currently under development, to be installed when it begins clinical trials (127).

Although CON laws (and their administration) appear to be encouraging some of these joint purchasing arrangements, the two do not necessarily coincide. Planners in southwestern Pennsylvania, for example, have attempted to encourage such shared purchase but have been unable to do so **(36).** Instead, this planning agency must attempt to set priorities for ownership of ESWL units among individual hospitals. The Health Planning Council of Greater Boston has similarly relied on setting priorities for acquisition. This planning agency, which produced the first thorough planning study for ESWL in the United States, determined that in the short run there existed a need for only one lithotripter in the area served by that planning agency, and that the hospital operating the unit would serve as a referral center for other hospitals in the area. Permission was granted to Massachusetts General Hospital to house the lithotripter, and that hospital became one of the six investigational sites in the United States to obtain Food and Drug Administration approval for ESWL. A second Boston area hospital has since received approval for and installed a machine (48,125).

In some areas limited joint purchase and shared use are not enough to obtain CON approval. The Virginia Department of Health rejected a proposal to locate an ESWL unit in the Virginia suburbs of Washington, DC, even though the unit was to be jointly purchased by two area hospitals and a group of area physicians and located at a large suburban teaching hospital (140). The justification for rejecting the proposal was that the proposed service area of 1..5 million population was not sufficient to support a extracorporeal lithotripter, especially since it was likely that one or more lithotripters would eventually be located in Washington, DC, itself (141). The Virginia Department of Health's rationale has since been supported by the fact that three Washington, DC, hospitals have received permission from the District planning agency to jointly acquire an ESWL unit, and the fact that hospitals in several nearby Maryland suburbs are considering ESWL purchases **(51).** Maryland requires licensure, but not CON approval, for major medical equipment,

A contrasting example is set by Chicago, in which numerous ESWL units may exist almost side by side. Two hospitals in Chicago already have approval for ESWL. One of these, Michael Reese Hospital, is a testing site for ,Medstone's ESWL device. The Chicago Health Systems Agency has recommended further approval for extracorporeal lithotripter purchases by three other major Chicago hospitals (all associated with universities), for a potential total of five devices in the metropolitan area **(56).** Finally, the Veterans Administration plans to install an ESWL unit at one of its hospitals in the Chicago area (102), a decision outside the control of the planning agency.[5] Thus, it is conceivable that six ESWL units could compete for patients within the same metropolitan area.

These examples illuminate the fact that generalities regarding the overall impact of CON laws on the diffusion and distribution of ESWL are difficult to make. In a few States, the planning process seems to be encouraging joint purchase of ESWL and may restrict the number of devices be-

[4]Uro-Tech, a private management company, holds partial ownership in a number of ESWL units, including the first three lithotripters located in tree'-5tanding ambulatory care centers on California NorthCarolina, and Florida) (4 I)

[5] Under Public Law 93-641, the National Health Planning and Resources Development Act of 1974, the VA was given voting membership on State health coordinating councils and on regional health systems agencies, A VA hospital was supposed to submit an application to the health systems agenc, for new construction or equipment. The agency made a recommend ation to the VA Central Office, which could approve or disapprove without regu la t ory constraint and did not have to explain its action" (180), VA s participation in the health planning process is voluntary and State plan- n i ng counci Is have no authority to disapprov e the installment o t an ESWL unit in a VA facility.

low the number that would have been acquired were there no planning laws. In other States, however, even those with fully functional CON laws, planning seems to be having no restrictive effect whatsoever. For the United States as a whole, it is unlikely that planning laws will restrain ESWL purchases below the numbers that various organizations have estimated would be sufficient (see ch. 5). The Blue Cross and Blue Shield Association, for instance, has suggested that the entire U.S. population could be adequately served by ***50*** ESWL units (14). But Dornier had 50 ESWL units installed in the United States by the end of 1985 and plans to have 100 in place by the end of 1986 (125). The existence of planning laws seems highly unlikely to restrict the overall number of devices to a minimum level.

A contrast to the U.S. planning experience with ESWL is provided by Australia. About 80 percent of acute health care in that country is provided in public hospitals, and expensive technology acquired by those hospitals must be approved and financed through the state governments (148). The Australian Department of Health's National Health Technology Advisory Panel has produced a full assessment of ESWL to assist the states in planning for the technology. The panel concluded that although the technology is "more expensive than percutaneous stone removal it appears to involve less cost than open surgery and offers significant patient benefit compared with both of these alternatives" ***(38).*** The panel estimated the number of eligible patients with upper urinary stones in each state in the Commonwealth of Australia and concluded that Australia had an annual demand for ESWL of ***2,500*** to 3,000 patients. Based on this figure and a target caseload of 1,200 to 1,400 patients per machine per year, the Panel concluded that (38):

> On the basis of current numbers of procedures for upper urinary tract stones, not more than three ESWL machines would be needed for Australia, two of which should be located in Sydney and Melbourne. However, geographical factors may result in a need for additional machines. The machines should be sited in hospitals which have well developed urology and radiology departments, with appropriate access to percutaneous (PCN), surgical and transurethral procedures.
>
> The number of machines required should be kept under review in the light of the length of time patients must wait for treatment and future technical developments. Availability of second generation equipment may became a significant factor in the medium term and could influence decisions of procurement of a third machine.

PLANNING AND THE DYNAMIC MARKET

Planning for ESWL, as with most technologies, is complicated by the existence of a dynamic market. In this case, the market is changing on five fronts:

1. technologies to reduce the recurrence of urinary stones, and consequently the overall incidence of stones;
2. improvements in invasive treatments for urinary stones;
3. the emergence of competing manufacturers of ESWL equipment;
4. experience in the most appropriate role for ESWL; and
5. modifications in the Dornier lithotripter to extend its uses.

Technologies to reduce the incidence of urinary stones among those people with frequently recurring stones are an important unknown in the stone treatment market. These technologies may be small in number and effect, or they may exert an important influence on the population. In the extreme, if preventive measures were successful, a significant proportion of second stones could be prevented, and the total number of patients needing treatment for problematic stones could be substantially reduced. Under the latter scenario, those patients who did have stones would likely be having their first experience with this problem, and they would be at less of a risk for untoward outcomes associated with invasive procedures. This consideration might affect decisions regarding

which treatments were most appropriate; fewer patients might be referred to ESWL out of a fear that multiple surgeries might endanger the kidney. Urologists disagree over whether preventive medications such as potassium citrate can prevent more than a small proportion of stones in the immediate future, Still, such medications remain a highly important treatment for study that may be both effective and cost savings for certain patients.

Improvements in current invasive alternatives to ESWL, particularly percutaneous removal of stones, may have a much larger and more immediate effect. In centers in which percutaneous lithotripsy is performed on high volumes of patients, by surgeons with sufficient experience and expertise, this procedure may be very comparable to ESWL in cost and clinical appropriateness. Percutaneous lithotripsy will have particular appeal to those urologists who do not have access themselves to ESWL and to hospitals who cannot justify or afford ESWL equipment. A danger of the appeal of percutaneous lithotripsy is that the lower costs, higher success rates, and broader use demonstrated by urologists performing this procedure in higher volumes may not be attained by less experienced operators in less efficient settings. Also, urologists without access to ESWL may be reluctant to refer patients to a urologist who does perform ESWL unless those patients are clearly unsuitable for more invasive procedures. If existing trends continue and percutaneous lithotripsy proves to be clinically and financially competitive with ESWL when performed by most physicians in most hospitals, the use of ESWL might decline despite the existing fixed costs of expensive equipment already in place.

In contrast to the above scenario, the existence of competing manufacturers for ESWL could dramatically expand the use of this technology. It is the high cost of ESWL equipment that draws the attention of third-party payers, causes ESWL to come under the jurisdiction of CON laws, and invites the scrutiny of planners where anticipated caseloads of equipment to be purchased are small. Competing manufacturers are emphasizing the lower cost of their equipment, which might justify the existence of many more machines. However, the competing lithotripters are not yet clinically proven, and their actual costs cannot be judged until these devices have been installed and used on a number of patients. The competing device apparently closest to marketing in the United States, the Medstone lithotripter, had treated only four human patients as of the end of 1985 (4). Thus, this device is unlikely to be available for general marketing before the end of 1986, even if it proves to be clinically effective.

Experience in the most appropriate uses of ESWL, both current and future models, is an important area of investigation, especially in light of the rapid evolution of percutaneous stone removal, Increased understanding of the limits of ESWL might lower its use relative to percutaneous procedures. Conversely, increased appreciation of its possibilities for treating difficult stones when used in combination with percutaneous and transurethral procedures may increase the use of ESWL.

Finally, the market for ESWL could be greatly expanded if the technology itself is extended to other uses. If protocols involving the use of ESWL on lower urinary stones, such as the one being conducted at the University of Virginia, are successful, the possible uses of ESWL will expand still further. An even more dramatic expansion of the technology is its application to gallstones, which afflict a larger number of patients in the United States than do upper and lower urinary stones combined (124).6 Extending ESWL applications to gallstones does not necessarily mean that both gallstones and urinary stones could be treated on the same machine. At present, a separate ESWL device specific to gallstones is a more realistic possibility; a gallstone lithotripter currently under development by Dornier has been tested on several patients in West Germany, with some success (147). It is not likely to reach clinical trials in the United States for at least a year (125). Still, if ESWL for gallstones became a reality in the near future, it might provide justification for ESWL, in some form, in most major population centers.

[6]In 1?83, 482,000 people were discharged from U.S. non-Federal acute care hospitals with a diagnosis of gallstones, compared with *330,000* people with a diagnosis of kidney and ureter stones and 18,000 people with lower urinary stones (124}.