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INSIDE

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CON Vs. Quality Assurance

As CON laws disappear, quality becomes more important in decisions

This may bring more work for quality managers

A growing number of states have begun to lift restrictions on what services hospitals can offer. It would be a good idea to pay close attention to what's going on in this arena in your state because quality issues come into play in all categories and stages of certificate-of-need (CON) deregulation. Without a doubt, your job will be affected by what's going on now and down the road. An important point: If your hospital is in a state where deregulation is allowing markets to open up, don't let the heat of competition force you to lower your standards or take short cuts in your accreditation and credentialing processes.

Under state CON laws, a hospital must demonstrate that its community has a special need for a given service for the hospital to be allowed to expand into new services and technologies such as magnetic resonance imaging, ambulatory surgery, or cardiac care. **(See related story, p. 202.)**

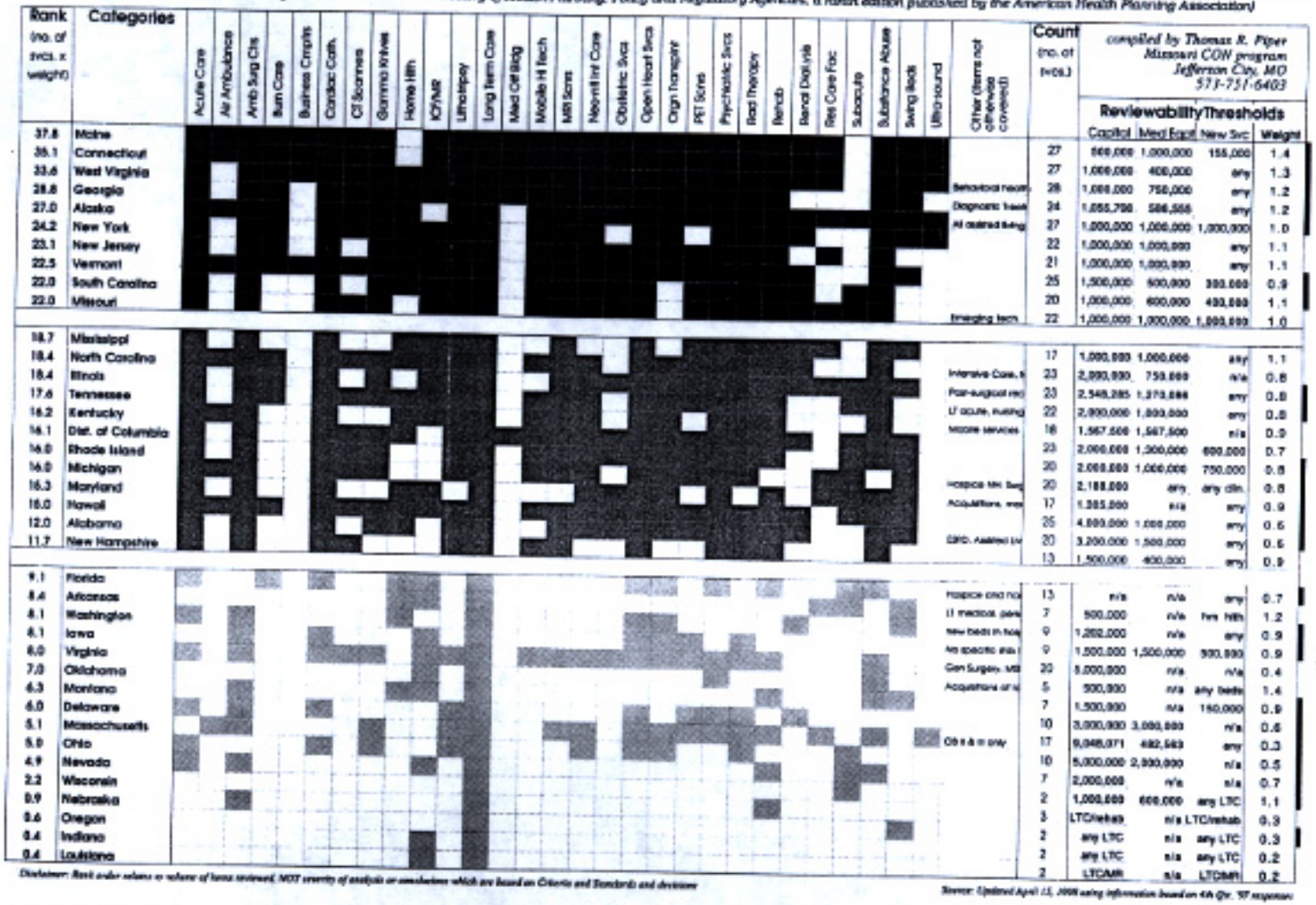
Hospital Peer Review asked **Mary Yost**, RN, spokeswoman for the Ohio Hospital Association in Columbus, how CON changes affect hospital quality and the jobs of quality professionals. "In many cases," she says, "where CON regulations are eased, they are being replaced by new quality standards." The legislature voted to deregulate CON for all facilities in her state (except for long-term care) in 1995. The lawmakers set up a gradual deregulation schedule, and in the place of CON, created a new system for setting up quality standards and public reporting on how hospitals meet those standards.

"So in one piece of legislation, they directly tied the two together," says Yost. "The move away from CON pointed us in the direction of new quality standards. The thinking at the time was that the move was in some ways an acknowledgement that CON was not accomplishing what it was intended to accomplish. What lawmakers were recognizing was that the state can play a role in quality oversight, but not through CON."

(Continued on page 199)

1998 Relative Scope and Reviewability Thresholds of CON Regulated Services

This information is summarized from the 1998 National Directory of Health Planning, Policy and Regulatory Agencies, a ninth edition published by the American Health Planning Association)



Disclaimer: Rank order relates to volume of items reviewed, NOT severity of analysis or conclusions which are based on Criteria and Standards and decisions

Source: Updated April 13, 1998 using information based on 4th Qtr. '97 responses

In the above chart, a white square means that state does not review the service named. A black square means the state does review the service. The rank order relates to the volume of items reviewed, not severity of analysis. The reviewability thresholds determine whether a particular project in that state requires review. The index gives $1M an equivalent weight of 1 and becomes a multiplier against the number of services a hospital provides. The index is applied to obtain an ultimate factor that tells how broad or narrow individual programs are as compared to others across the country. The states are ranked from the top to the bottom to show how comprehensive state programs are.

Source: 1998 National Directory of Health Planning, Policy and Regulatory Agencies. 9th ed. Falls Church, VA: American Health Planning Association; and Tom Piper, director, CON program, Missouri Department of Health, Jefferson City.

But the new state quality measures are coming slowly, she says. "The legislature has spoken about the direction it wants us to move in, but putting it into effect is another story. It can't be done overnight." What the state of Ohio has accomplished to date is to create the rules that spell out what the quality standards are. Next, the state will have to determine what kinds of data it will ask hospitals to provide to measure compliance with the standards.

"That's complex stuff," says Yost. "Once those systems are up and running, there will be more work for quality managers because they'll have to make sure they're doing everything they need to do to comply with the new law. Today, no. We're not there yet."

'We look at things differently now'

Patti Higginbotham, RN, CPHQ, director of quality improvement at Arkansas Children's Hospital in Little Rock, says her role has changed somewhat over the past few years since CON deregulation in Arkansas. "We look at things differently now," she says. "Expanding our services has caused us to question how we should evaluate quality – what indicators we should look at and measure and what the priorities are."

With so much going on, issues of priority are especially difficult, she says. "It's hard to know what's more important than something else when they're all important. How do you determine what activities and measures and improvements deserve more of your time?"

Arkansas Children's Hospital applied for and got CON approval to increase its neonatal bed space. "We have to ask ourselves, 'What was the goal in asking for that expanded service? Why was that important?'" says Higginbotham. As a part of planning for new programs and services, the quality department has to look at why the facility wants to do what it's doing. It has to figure out what kinds of quality measures it needs for those new services to show that the facility is achieving goals in terms of actual patient care and cost.

"We have a long way to go in learning how to evaluate new business plans," she says. "We're good at tracking them financially, but we have to stop and consider *why* we're taking a certain road. Are we going to reduce hospitalizations for a certain group? Are we going to improve clinical outcomes over time? Are we going to increase patient satisfaction? Reduce waste? It's easy to get tied up in the improvement activities – how we're going to measure and report – but you have to spend more time on looking at the why's."

David B. Nash, MD, MBA, associate dean and director for health policy at Thomas Jefferson University in Philadelphia, agrees that there may be more work for quality managers when CON laws are lifted, but quality professionals also are involved prior to that point, when hospitals apply for the addition of new procedures. "When a hospital applies to the state for a new building for a procedure," he says, "it has to submit historical information on that procedure's quality. The CEO or director of planning typically comes to the quality managers or directors for that information, and they have to supply specific data about how many cases the hospital has done, what the complications have been, the success rate, and so on."

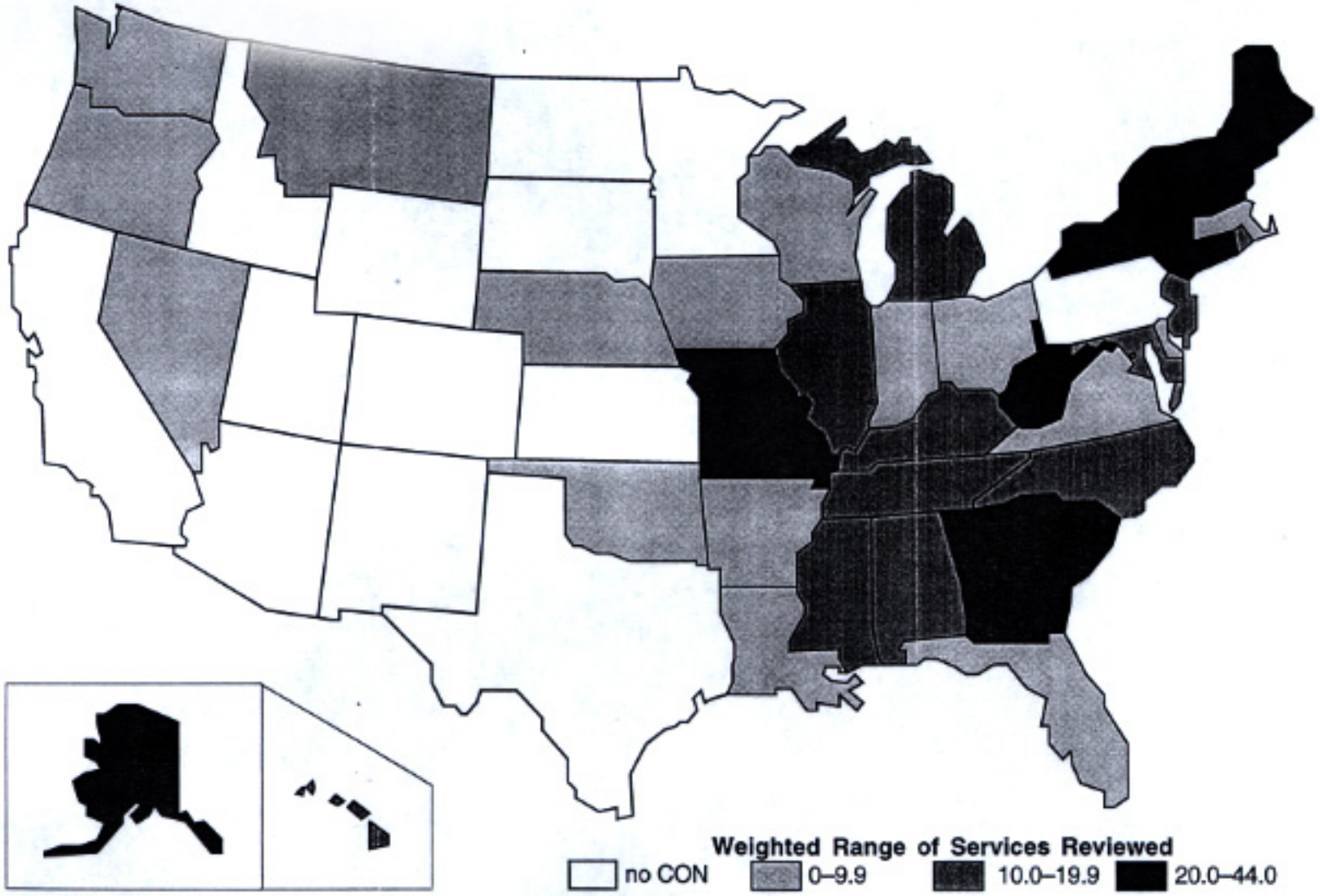
Credentialing and tasks regarding job classifications also are affected by CON laws on the books. For example, if your facility gets approval to begin to provide maternity services, you will have to make sure you have specially credentialed nurse managers with a specified number of years of experience. Those staffing requirements make credentialing a big part of the quality standards.

Ted Ackroyd, director of Harrisburg, PA-area data analysis firm QuadraMedi Corporation, says if a facility's CON application is denied, "it may well be that the individuals who were going to provide that service will either continue doing what they were doing previously or be transferred to some other operation within the system. Certain narrowly trained individuals may lose their job due to CON development, but that would be more the exception than the rule."

For QI to go smoothly, quality planning must be done well. **Barbara Niedz**, PhD, RN, director of quality management at St. Joseph's Hospital and Medical Center in Paterson, NJ, explains that CON laws make quality planning one of the three facets of quality at her facility, the other two being quality improvement and quality control. Planning, she says, involves making sure you have identified clearly who your customers are and what their needs are, then being sure you've

(Continued on page 201)

1998 Relative Scope and Thresholds of CON Regulation



revised March 4, 1998

Source: Tom Piper, director, CON program, Missouri Department of Health, Jefferson City.

designed services and processes to deliver those services to meet those customers' needs.

"For example," says Niedz, "we made a CON application for pediatric cardiology two years ago, and it was approved. St. Joseph's went through extraordinary lengths to collect data for that application. Of course there was no historical data, because pediatric cardiology hadn't been one of our services." The data that had to be collected and presented had more to do with how many pediatric cardiology surgeries occurred over past years in the state. The organization had to determine how many patients needed the service in the state historically and where they went for the services. "That's the kind of quality data that goes into quality planning documents," she explains.

Since St. Joseph's implemented its pediatric cardiology program, the quality department has had to institute measures to monitor the quality of that new service. "Now it becomes a part of quality improvement and quality control," says Niedz. "If a good job has been done in quality planning, the job for the quality improvement folks is made easier — your outcomes are good from the outset, and all you're doing is monitoring."

Thirty-seven states still require approval of specialized services under CON laws, but restrictions among those states are beginning to loosen. **(See map and grid showing which states retain CON regulations and which are in transition, pp. 198, 200.)** Efforts to eliminate the review process altogether failed this year in several states, including Georgia and Washington. New York and Connecticut maintain their CON laws, but have taken steps recently to streamline them. **(See related articles on the status of CON regulations in Pennsylvania, Vermont, Ohio, and New Jersey, pp. 202-206.)**

Opponents of CON laws say, "Let's level the playing field and keep markets competitive." They view the approval process as cumbersome and costly. Managed care has taken over the job of squeezing out costs and has made any cost-effectiveness motives on the parts of lawmakers obsolete. The regulations, they say, impede their efforts to compete aggressively for patients and managed care contracts. **Lou Marturana**, a consultant with the Health Care Quality Institute in Edison, NJ, says health care services seem to be market-driven, but when CON is lifted, the demand for services often escalates. "Let's remember that everyone went to Texas for cardiac services 10 years ago," he says.

The new freedoms associated with deregulation have profit potential and give hospitals greater flexibility to compete. Says one opponent of CON who wished to remain anonymous, "General hospitals have become dinosaurs – big bodies, small brains." Another opponent, who also asked to remain anonymous, asks how the government expects hospitals to be more competitive while denying them the tools required for competition. The barrier to an open market, he says, often has little to do with quality or cost, but really is aimed at protecting existing providers from competition. Powerful for-profit hospital systems such as Nashville, TN-based Columbia/HCA, for example, have been lobbying for years to rescind CON laws in states that affect their facilities.

CONs protect more than status quo

On the other hand, some want the CON laws to stay on the books and oppose "the selfish skimming off of profitable services" by boutique facilities. Some observers say the proliferation of facilities that are focused on well-insured patients with particular conditions amounts to "medical gentrification," and that such a situation could destroy the financial and medical underpinnings of full-service hospitals.

Observes a CON proponent, who wishes to remain anonymous, "My community needs another hospital about as much as it needs a multimillion-dollar macarena dance hall." Easing of CON regulations lowers quality, they these deregulation opponents contend, as well as draining patients and money from the larger hospitals that need that revenue in order to continue to fund training and research.

Political interests, driven by economic forces, exert a powerful influence on the sunsetting and rescinding of CON laws. State CON laws came to the fore about 20 years ago. They were designed to regulate unwarranted growth in the medical industry and hold down unnecessary health care costs. State lawmakers were trying to hold down costs by imposing restrictions to keep hospitals from offering duplicative services in the same geographic area. The authors of CON laws intended to protect quality care and provide public accountability through regulation of new services and negotiation among competing interests. ■

PA's in the 'wild, wild West for cardiac surgery'

The question: More regulation or less?

A source who requests anonymity told *Hospital Peer Review* he thinks there's a dangerously low level of regulatory oversight in Pennsylvania. "Quality managers in some states complain of redundant regulation," he says, "and some would say that Pennsylvania has a more rational situation. But considering the changes going on in the fundamental structure of health care delivery — consolidations, expansions, and integrations — we don't have nearly enough oversight."

Ensuring that quality of care is not jeopardized in the face of these financial difficulties and new arrangements is a severe challenge. Managed care is putting strains on hospitals and physicians to reduce utilization. This is not the time for less regulation, he says, but rather for more regulation or at least different regulation.

The source, a health care analyst, tells *Hospital Peer Review* that this summer, the state government decided that the Department of Health would no longer do routine hospital inspections. They would leave it up to the Joint Commission on Accreditation of Healthcare Organizations in Oakbrook Terrace, IL.

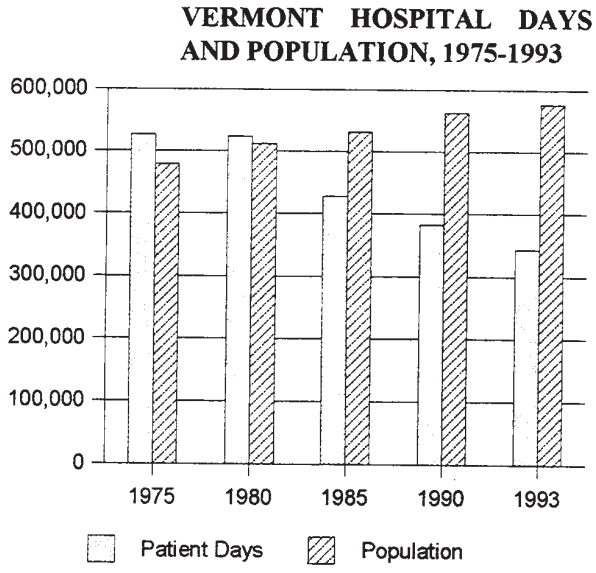
Deregulation leads to proliferation

Pennsylvania's certificate-of-need (CON) approval requirement was allowed to sunset a couple of years ago, and since then at least six hospitals in that state have begun offering bypass surgery. **David B. Nash**, MD, MBA, associate dean and director for health policy at Thomas Jefferson University in Philadelphia, has commented that Pennsylvania is in the "wild, wild West at this point for cardiac surgery."

Ted Ackroyd, director of QuadraMedi Corporation, a Harrisburg, PA-area data analysis firm, says the result of allowing CON to sunset in Pennsylvania is an increase in the number of services offered. "Supply has increased," he says. "Has demand increased in an equivalent and proportional manner? Not likely." More providers are doing fewer services, he says, so they're probably not getting appropriate experience or are being continually challenged.

Tom Piper, director of the CON program in Missouri's Department of Health and past president of the American Health Planning Association in Falls Church, VA, says, "When Pennsylvania's CON was permitted to sunset in late 1996, they were stunned. What do you do after CON? One statement was repeatedly made: If the CON did anything really well, it was to make sure that planning was a visible part of the acquisition process — for equipment and capital expenditures."

Under CON, planning questions were asked throughout the process. Officials had to make sure the plan in place was good. "Without CON," says Piper, "where do you find that planning resource?" They're now working in Pennsylvania



The use of inpatient care in Vermont is shrinking even while the population grows, probably because of changes in medical practice. For example, in the 1970s a gall bladder removal typically involved an eight-day stay. By the mid-1980s the stay was reduced to four days by virtue of quicker discharge and performing the operation on the day of admission. Today only one or two days are needed, due to the preference for laparoscopic and laser surgery.

Source: Vermont Health Care Authority. Health Resource Management Plan, 1996-1999. Montpelier: March 15, 1996.

to convert what was previously the CON into quality and licensure standards.

Hospital Peer Review asked **Stan Lane**, director of the CON department for the state of Vermont in Montpelier, if he thought quality was suffering as thresholds for review are being raised.

Where do you draw the line?

"In a number of high-tech areas, we do have concerns about maintaining expertise as volumes decrease," says Lane. "If you do only 10 heart surgeries a year, there's some question about whether your staff has enough experience to do a good job. That would hold true for other high-tech procedures as well." There's discussion in a number of sections of Vermont's Health Resource Management Plan about making sure providers have enough expertise and that the volumes are there. **(See chart on Vermont's hospital days and population, p. 202.)**

"There's reason to have regulation of some sort," says Lane, "especially oversight of organizations providing the more complicated services. A lot of states have moved away from CON laws and toward quality, licensing, and professional certification instead. Those are other routes toward regulatory oversight."

In Vermont, health care facilities are subject to CON review when they propose any new construction or the acquisition of diagnostic or therapeutic equipment costing more than $250,000. They also have to apply for any new health service that has an annual operating expense of more than $150,000.

Lane says, "We raised the thresholds for review for the CON in Vermont two years ago." For example, before 1996 the state would review any capital expenditure by any health care facility that exceeded $300,000. That threshold was raised to $1.5 million in hospitals and $750,000 in other facilities. ■

'Pure-play' facility focuses for profit

Is a niche care facility in your area's future?

There's a nationwide move toward innovative attempts on the part of nonprofit hospitals to find new sources of capital now that managed care has caused a drop in inpatient stays and reimbursement rates. This often takes the form of partnering with clinics focused on specific diseases. Critics of the trend say it leaves cash-starved hospitals in its wake and undermines the money-making services hospitals need to support costly research and less remunerative departments, such as emergency medicine.

Following are examples of the trend:

• Montefiore Medical Center in New York City has teamed up with Bentley Health Care of Beverly Hills, CA, to open a string of 24-hour clinics devoted to cancer care and treatment of HIV and AIDS in the New York area.

• Columbia-Presbyterian Medical Center, also in New York City, has opened a center for women's health.

• Winthrop University Hospital in Mineola, NY, has opened a heart institute and in five years has tripled its volume of open-heart surgery.

• Renaissance, a unit of Universal Health Services in King of Prussia, PA, is launching specialty hospitals for women and children.

In addition, facilities such as Charlotte, NC-based MedCath look for markets with no certificate-of-need regulation and provide cardiovascular services in "boutique" heart hospitals across the country. MedCath owns heart-specialty hospitals in Little Rock, AR, Tucson, AZ, and McAllen, TX, each with about 60 beds. At least 80% of their services are cardiovascular, and one-third of procedures are outpatient. MedCath plans to open five similar facilities elsewhere in the United States. MedCath also manages medical practices and fixed-site cardiac diagnostic and therapeutic centers, and operates mobile cath labs. MedCath's revenues rose from about $26 million in 1994 to $111 million last year.

Other so-called "focused factories" or "pure-play companies" are HealthSouth of Birmingham, AL, Intensiva of St. Louis, and Pediatrix of Fort Lauderdale, FL. ■

NJ regs impose volume requirement for credentials

New standards threaten urban hospitals

Part of a new piece of legislation that went into effect in New Jersey in July is a requirement that each hospital wishing to be certified to perform heart bypasses must perform at least 350 a year, up from 250 under previous rules. In addition, surgeons now are required to perform at least 100 bypasses at each hospital where they practice to be credentialed. There were no volume requirements for physicians before that time. From a practical standpoint, the new requirement will have little effect on existing cardiology programs, because all but one (University Hospital in Newark) already do over 350 a year.

Proponents of certificate-of-need (CON) laws fear quality may suffer if the laws are rescinded or abridged. July's legislation in New Jersey follows on the heels of the release of a report commissioned by the state in which researchers noted a clear connection between the volume of three surgical procedures performed at hospitals in the state and surgical success. The report focused on coronary artery bypass graft surgery, percutaneous transluminal coronary angioplasty, and cardiac catheterization. **(See three charts with statistics on those procedures, below right.)**

The report's authors — **David B. Nash**, MD, MBA, associate dean and director for health policy at Thomas Jefferson University in Philadelphia, and **Ted Ackroyd**, PhD, director of QuadraMedi Corporation, a Harrisburg, PA-area data analysis firm — suggested in the report that minimum volumes for hospitals could be raised to as high as 800 operations a year and that surgeons should be doing at least 125 bypasses annually. The study found that the risk of death decreased steadily as the volume of surgeries at centers increased. For example, according to the authors, a patient whose surgeon performed more than 126 bypasses a year was 3.1 times less likely to die than a patient whose surgeon did fewer operations.

Many other outcomes studies also have shown that quantity drives quality and that patients have better outcomes at hospitals that perform high volumes of procedures. In response to the accepted volume-outcome hypothesis, the states whose CON laws have been allowed to sunset or have been rescinded have stricter licensing procedures that increase their oversight of new services.

The legislation signed by New Jersey Gov. **Christine Todd Whitman** ended the requirement that hospitals win state approval to open pediatric and maternity wards and to expand other services such as ambulatory surgery and magnetic resonance imaging. CON laws are eroding in New Jersey, but they're not gone yet; CON approvals still are required for cardiac surgery, organ transplants, neonatal intensive care, and other highly specialized services. A new state commission is studying whether state approval of CON should remain mandatory in those areas.

Suzanne Ianni, executive director of the Hospital Alliance of New Jersey in Trenton, says New Jersey is deregulating services in three phases. In the first phase, legislation states that the addition of certain services will no longer require a CON, but will be subject to licensure by the Department of Health and Senior Services. Those newly unregulated services include acute renal dialysis, magnetic resonance imaging, detoxification for drugs and alcohol, and ambulatory

Linking Volume to Outcomes in New Jersey

Annual volume of CABG, PTCA, and cardiac catheterization

	1993	1994	1995
Bypass surgery	7,638	7,886	8,518
Angioplasty	9,211	11,064	12,641
Catheterization	37,964	38,054	37,969

Mortality rates by procedure and year

	1993	1994	1995
Bypass surgery	5.0%	4.8%	4.9%
Angioplasty	1.3%	1.3%	1.5%

Rates of complications of care by procedure and year

	1993	1994	1995
Bypass surgery	57.9%	41.1%	39.4%
Angioplasty	16.6%	14.4%	15.1%
Catheterization	14.1%	11.1%	11.2%

Source: Nash DB. *Cardiac Surgery in New Jersey.* New Jersey Department of Health and Senior Services, Trenton.

care. The intent of phase one is to deregulate services already under expedited review, says Ianni, and allow a quicker review time without public comment period.

Phase two provides that within 20 months of enactment, certain services will be exempt from CON requirements. They include obstetric and pediatric services, extracorporeal shock wave lithotripter, hyperbaric chamber, and positron emission tomography. The intent, says Ianni, is to look carefully at those services before deregulating them and strengthen their licensing standards. The third phase concerns big-ticket items that have a large impact on the state budget or are highly specialized, such as cardiac catheterization, organ and bone marrow transplant, and burn treatment. During that phase, a CON study commission will be set up to look at such expensive and specialized services to decide what to do with them, says Ianni.

CON's special effect on urban facilities

Urban hospitals in New Jersey as well as in other states are opposed to easing CON requirements because these hospitals stand to lose patients and revenue if restrictions are lifted. Though suburban and rural patients appreciate the convenience of having special services close to home, "the Hospital Alliance of New Jersey feels strongly that CON is important for urban hospitals," says Ianni. "The state has placed tertiary services in urban hospitals, and they bring a paying patient base from the suburban areas. That money helps subsidize the care of uninsured patients and the underserved. Once you start replicating services in the suburbs, there's no reason for patients to go to the urban areas."

Ianni points out that the benefit of CON laws is that the state has an opportunity to consider the need for new services before investments are made in them. Without regulation, she says, there would be a proliferation of unnecessary services, which would only add to health care costs. "There's a direct correlation between volume and quality of care," says Ianni.

The open-heart competition in New Jersey has spurred a pilot program called the Inner City Cardiac Satellite Demonstration Project. Under the program, an inner-city hospital licensed to provide cardiac surgery will partner with a nonurban provider within its system and create a suburban or rural satellite. Revenues generated at the satellite must be plowed back into the urban provider. If the urban hospital's volume slips more than 20% in a year, the satellite will be discontinued. ■

Ohio: 'An extraordinary glut of capacity'

'Boutiques' will affect services offered

Is hospital quality in Ohio suffering now that certificate-of-need (CON) requirements have been downscaled? "It depends on the extent of the service," says **Tom Piper**, director of the CON program in Missouri's Department of Health and past president of the American Health Planning Association in Falls Church, VA. "I'd say a community hospital doing open-heart is probably overextending itself."

In the wake of deregulation, Ohio's Department of Health is developing quality standards and proposing rules for licensing of six types of facilities and nine service categories. The agency is drawing upon accreditation organizations such as the the Joint Commission on Accreditation of Healthcare Organizations in Oakbrook Terrace, IL, existing state licensure programs, and Medicare to develop its quality standards, which will include quality assessment and improvement, contracts, fire safety, records management, the granting of variances, and disclosure requirements and informed consent.

Piper says the state is seeing a strong tendency for physicians to jump ship, form their own groups, and set up independent surgery locations. "They can work bankers' hours, be very selective about the clientele, and not have much responsibility by way of uncompensated care," he says.

Piper says one study showed that there's no immediate evidence of any negative effect after deregulation. His reply? "To that I say 'baloney,' and Ohio is probably the most acute example." Ohio has been ratcheting down its CON program over a period of three years. "What they have wound up with now is an extraordinary glut of capacity," says Piper. The number of MRIs has

gone up by 50%, and the number of psychiatric beds has gone up by 500.

Ohio has nearly finished phasing out its CON laws. Some suburban and rural community hospitals can now offer cardiac bypass surgery, and for-profit systems are building boutique facilities that focus on a niche specialty, offering, for example, only cardiac care or orthopedic surgery. In some Ohio towns with two hospitals, both may offer obstetric care or kidney dialysis. The state discontinued regulating the expansion of kidney dialysis stations beginning in 1995, and since that year 847 stations have opened, according to **Gretchen McBeath**, a lawyer for the Ohio Hospital Association in Columbus.

Susan Mikolic, quality standards specialist for Lake Hospital Systems in Painesville, OH, says they're not seeing boutique facilities in her area of the state just yet, "but what we are seeing is an increasing expansion of existing facilities into different programs and areas for which they were unable to obtain a CON formerly. Now there's nothing stopping them." For example, suburban facilities are now able to offer obstetric and cardiac services to satisfy patients who didn't want to go into downtown Cleveland. "Until now, facilities close to home were unable to obtain CONs for those services."

A health care building boom is in process in some parts of the state. **Mary Yost**, RN, a spokeswoman for the association, says, "What we're seeing is not only construction in the areas of ambulatory surgery and outpatient care centers, but also proposals for new hospitals. That was not anticipated."

The new hospitals are not general care facilities, but boutique hospitals that offer specialty services. Yost says Charlotte, NC-based MedCath caused some tremors in Dayton recently when it proposed to build a freestanding heart hospital in that city, but MedCath eventually partnered with existing hospitals instead. **(See related article, p. 205.)** "The uproar subsided considerably because of the partnership arrangement," says Yost. "But now there's a new MedCath proposal in Columbus for a freestanding heart hospital." And another proposal for two new hospitals that would be maternity or women's health centers are in the offing. "People are wondering what those will do to existing hospitals and their ability to provide a full range of services if key services are siphoned away from them," says Yost.

The types of facilities under new licensing rules in Ohio are ambulatory surgical facilities; freestanding dialysis centers, inpatient rehabilitation centers, birthing centers, and radiation therapy centers; and mobile or freestanding diagnostic imaging centers. Among the nine service categories are obstetrics and newborn, open heart procedures, solid organ and bone marrow transplant, radiation therapy, diagnostic imaging, and dialysis. ■

Cesarean rates may be misleading

Unadjusted figures can skew findings

A recent study suggests that unless cesarean section rates are adjusted for clinical factors, comparing them may be a flawed method for grading the performance of hospitals.[1]

Failing to account for patient characteristics that drive up cesarean rates can produce misleading results. "Rankings that fail to account for clinical factors that increase the risk of cesarean delivery may be methodologically biased and misleading to the public," say the researchers from Case Western Reserve University and the Quality Information Management Program, both located in Cleveland.

The study ranked 21 Cleveland-area hospitals based on the traditional ratings method, then compared those results to rankings that adjusted for the presence of patient risk factors such as maternal illness, maternal substance abuse, breech birth, or fetal abnormalities. There were considerable differences. For example, two of the 21 hospitals deemed subpar under the old system rose to levels of acceptable quality, while two others dropped from acceptable status to substandard status. The study found that the overall cesarean delivery rate was 15.9%, but varied from 6.3% to 26.5% among the different hospitals.

Reference

1. Aron DC, Harper DL, Shepardson LB, et al. Impact of risk-adjusting cesarean delivery rates when reporting hospital performance. *JAMA* 1998; 279:1,968-1,972. ■

Prepare for surprises during your JCAHO surveys

Plan a few extra contingencies

Sandra Sessoms, RN, CPHQ, assistant vice president of nursing, quality improvement, and utilization review at Suburban General Hospital in Pittsburgh, relays some advice: "Make sure you have an extra team prepared to present to a Joint Commission survey team in case what happened to us happens to you."

The quality team at Suburban recently had an experience that Sessoms says she has not heard of happening to anyone else. The facility was surveyed by the Joint Commission on Accreditation of Healthcare Organizations in Oakbrook Terrace, IL, three years ago. On the second day, the visiting team told them they had done such a fine job in their performance improvement overview that instead of two teams presenting, they wanted to hear from a third team.

"Luckily, we had one in the wings," says Sessoms, "but of course those people were not as prepared to speak as the teams who anticipated making presentations. I knew which teams were stronger in presentation skills than others, and I chose from among those to do the third presentation. That was kind of tricky."

One of the teams that was prepared beforehand to make its presentation talked about the facility's total hip arthroplasty program, and the other gave a speech on a preadmission program for total hip and knee replacement. "The team we had to add at the last minute made its presentation on a flash sterilization project headed by the infection control committee, where we assessed how much flashing we were doing and its appropriateness," says Sessoms.

Wilma McCullough, quality assurance manager at Monsour Medical Center in Jeannette, PA, adds an experience that her facility had recently. "It's a bit difficult when a surveyor brings along someone in training. The problem is, we weren't warned that there would be an extra person prior to the survey, and we weren't prepared." The team at Monsour tries to keep two staffers with each surveyor at all times. That way, if one staffer has to leave for some reason, there's still one left there with the surveyor.

"Being unprepared for the additional surveyor was difficult because before we knew it, they were going in different directions, unaccompanied." McCullough's advice: Anticipate an extra surveyor showing up and have extra people on hand prepared to accompany him or her. ■

THE QUALITY - CO$T CONNECTION

Plan for data collection

Gathering data can cost a bundle

By **Patrice Spath**, ART
Brown-Spath Associates
Forest Grove, OR

It's a common occurrence — a medical staff committee, performance improvement team, or hospital department asks the quality management staff to gather information for a special study. To ensure that the study yields worthwhile information, it is important that several questions be answered by the people who are requesting the data. Without a clear understanding of the purpose and scope of the study, the quality management department may gather data that do not answer the questions being posed by the users of the study results.

The questions that must be considered before beginning data collection are listed below. The group that will be analyzing the study results comprises people who must answer these questions. The more specific they can be in answering each question, the easier it will be for the quality management staff to design a worthwhile performance measurement project. Sample answers for an outcome study involving patients who underwent hip replacement are illustrated in italics.

- **How do you plan to use the data?**

The study oversight group should articulate its purpose for performing the study, such as what it hopes to discover about an aspect of health care performance that it doesn't already know. An objective, narrowly focused purpose statement is a vital first step for the data collection plan.

Our purpose is to determine the short-term (six weeks post-op) functional status of patients undergoing hip replacement during 1998 and determine if there are

differences in outcomes related to patient age and discharge disposition.

• **What are the primary questions you expect to answer with this study?**

To prevent the collection of "wouldn't it be nice to know" data, the study group should focus its attention on no more than three important questions to be answered by the evaluation. Without a clear direction, the group could find itself with an abundance of information that doesn't tell it what it wishes to know.

Three questions to be answered by this outcome study:

— What is the short-term functional status of patients undergoing hip replacement in 1998?

— Does patient age affect short-term functional status?

— Does patient discharge disposition affect short-term functional status?

• **What patients will be included in the assessment?**

What inclusion and exclusion criteria will be used to determine the eligibility of study participants? Determine the patient population to be included in the study. Consider age category, gender, principal and secondary diagnoses, principal and secondary procedures, level of care setting — inpatient or outpatient — providers, and other characteristics.

For the hip replacement outcome study, all patients undergoing hip replacement in 1998, excluding those who expired post-op and those admitted from and discharged to a nursing home, will be included in the evaluation.

• **How many patients are expected to be included in the assessment process?**

Does this population represent an adequate sample size? In general, if the study population is small — fewer than 30 cases — the entire population should be studied. As populations grow larger, sample at least 10% of the affected population or 50 patients, whichever provides the larger sample. Remember, even when all patients from a particular time period are being studied, this population is still considered a sample from all possible cases that could be studied.

The group conducting the hip replacement study determines that, based on historical data, 15 patients per month will meet the inclusion criteria. It should be expected that in 12 months, 180 patients will be included in the study.

• **To answer the questions posed by the study group, what processes are of primary interest?**

If the study group wishes to determine the effect of certain health care processes on patient outcomes, it is important that the group delineates the activities of interest. If the answer to this question is not already clearly answered by the group's original study questions, find out what process-related data need to be gathered.

The hip replacement study group is primarily interested in the relationship between patients' discharge disposition and patients' functional outcomes. To ensure all relevant data are gathered, the group selects the following disposition categories they want information about: discharged to subacute care/rehab facility, discharged to home with home care, discharged to home with rehabilitation provided in outpatient clinic, discharged to home without home care or outpatient rehabilitation.

• **How will data about the processes of primary interest be gathered?**

Will you be using an existing data source, or will a new data source need to be developed? Although it may seem as if every possible data element is now being gathered by hospital information systems, there may be times when the data needed for a particular study are not readily available. First determine if the necessary data in an existing information system are accessible. Check to be sure the data definitions are consistent with what you need for the study. For example, if you are conducting a study of nosocomial infections, most infection-related ICD-9 codes (for example, 599.9, urinary tract infection) don't specify whether the infection originated in the hospital.

The hip replacement study group wants to know very detailed information about patients' discharge disposition. The disposition codes in the hospital's financial systems are too general to allow them to be used in the study. A new instrument will need to be designed to capture disposition details. To obtain the needed data, it may be necessary to review records of discharged patients.

• **To answer the questions being posed by the study group, what outcomes are of primary interest?**

The outcomes of interest may be well defined by the group's original study questions. If not, now is the time to obtain further details.

As evidenced by the study questions, the hip replacement study group is interested in patients' short-term (six-week post-op) functional status.

• **How will these outcomes be measured?**

This is the time for the study group to be sure it has supplied an objective definition of the outcomes it is interested in learning more about. Terms such as "quality of life" and "functional

Performance Measurement Study Design Checklist

Has the individual or group requesting the performance measurement study:
☐ Clearly stated what they hope to learn?
☐ Defined no more than three specific questions they want answered?
☐ Exactly described the group of patients to be included in the study?
☐ Determined the size of the study population and sampling techniques (if applicable)?
☐ Selected the processes of interest?
☐ Identified the data source for processes of interest?
☐ Selected the outcomes of interest?
☐ Objectively defined the outcomes of interest?
☐ Identified the data source for the outcomes of interest?
☐ Clarified data collection responsibilities?
☐ Secured the support of caregivers throughout the continuum of care if long-term outcome data are to be gathered?

status" may have very different meanings for each member of the study group. That's why it is important not to make assumptions about the data definitions.

Outcomes are the results of the medical care process. Outcome assessment emphasizes the effect of process on patients' well-being and quality of life to determine how the patient was affected by the process of care variables.

The study group should objectively define what it means by the term "outcome." The outcomes to be measured can include the clinical gains made during a specified time period, satisfaction that patients experienced with treatment processes, and the long-term benefit of a given treatment course.

There are many types of outcomes that can be measured:

- physical outcomes — biological indicators such as visual acuity post-cataract extraction;
- clinician-reported patient outcomes — the caregiver's judgment of how well the patient is doing clinically;
- patient-reported outcomes — how satisfied patients are with their quality of life restored and services rendered;
- financial outcomes — the cost of the health care intervention and the cost-benefit of the treatment course as compared to the outcome.

In the hip replacement outcome study, the focus is on patients' short-term functional status. The study group determines that the following elements of functional status will be measured six weeks postoperatively: patient-reported limitations in physical activities, limitations in social activities, and limitations in usual role activities.

- **Will you be able to use an existing data source, or will there be a need to develop a new data source to gather the needed outcome data?**

When measuring immediate outcomes of hospital care, it is likely that many of the data elements can be found in existing data sources. Mortality, length of stay, cost of care, and other outcome data are data elements in most clinical-financial databases. Patient-reported outcome data, both immediate and post-discharge, are harder to obtain because such information is not routinely among the gathered data. In these instances, new data-gathering instruments must be developed.

Use existing instruments when possible

Many facilities are using long-term patient outcome data collection instruments that are already developed and tested by health service research. By using existing instruments, the facility can save the time, labor, and expertise involved in developing its own valid and reliable data collection instruments. Also, using a standardized tool allows the facility to compare its results with those of other providers. Don't spend time designing your own outcome measurement tools when a number of already-validated survey instruments are available.

At the hospital where the hip replacement outcome study is being performed, post-hospital caregivers are not currently using any instrument for gathering short-term functional status data for patients undergoing hip replacement. Therefore, the study group agreed to evaluate already-developed patient-reported functional status measurement tools and select the instrument that would be best for gathering the data elements needed for their study.

- **Who will assume responsibility for collecting the necessary data?**

In many instances, the quality management department can assume full responsibility for gathering needed data elements. This may include developing new data sources, reviewing close records, or transferring information from one database to another. However, post-discharge outcome data may need to be captured by people outside the hospital. For example, a study of

postoperative wound infections may require involvement of physician office staff. The cooperation of providers throughout an episode of care is an important success factor in long-term patient outcome studies.

For the hip replacement study, orthopedic physicians agreed to administer a functional status measurement survey when patients returned to the clinic for the six-week postoperative checkup.

Setting the performance measurement study wheels into motion can be a labor-intensive process. Though it may take some time to get the study group to lay the groundwork for data collection, this planning process is time well spent. **Use the checklist on p. 209 as a reminder of all the issues that need to be addressed prior to embarking on the performance measurement project.** Gathering data costs money in terms of staff time and computer resources. To ensure effective use of your quality management resources, be sure that the people asking for performance data first answer these few critical questions. ■

NEWS BRIEF

Device prevents awakening during surgery

You may soon have a device that promises to alleviate anxiety for surgery patients — and improves outcomes. Anesthesiologists may at last be able to gauge doses of anesthesia more accurately so that this scenario can be avoided: the surgical patient who unexpectedly regains consciousness but is unable to communicate. The Bispectral Index, introduced at Strong Memorial Hospital in Rochester, NY, helps doctors calibrate doses to prevent patients from regaining awareness in the operating room. A flexible sensor attaches to the patient's forehead and records EEGs, giving anesthesiologists a direct measure of how deeply the patient is asleep.

Studies conducted at Emory University in Atlanta have shown that monitoring patients with the device improves outcomes – patients recover better and are eligible for earlier discharge from the recovery room because of their more alert status.

Doctors previously relied on blood pressure and other vital signs to monitor anesthetized sleep level and have tended to administer slightly more anesthetic than needed to avoid the chance of patient awareness during surgery. This new method measures the effect of pain killers only, not the full combination of pain killers, sedatives, and paralytic drugs, and allows anesthesiologists to customize drugs.

Unexpected wake-ups occur in at least 40,000 of the nation's 20 million surgeries. ▼

Medicare payments will increase in 1999

More than 5,000 acute care hospitals will receive an increase in their Medicare payments next year, according to an announcement by the Department of Health and Human Services. Most hospitals will receive a 0.5% increase in their base payment rates. An estimated 360 hospitals, many of whom have lost money on Medicare patients in recent years, will

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receive a 0.8% increase. Medicare's prospective payment system pays hospitals a predetermined amount for each Medicare discharge based on the patient's diagnosis. Hospitals in large urban areas receive slightly higher payment rates than those in other areas. The increase comes in the wake of newly published data from the Medicare Payment Advisory Commission showing that profit margins for hospitals in fiscal 1998 were 15.9% — the highest since Medicare instituted its prospective payment system in 1984.

For more information about Medicare billing, you might want to attend a conference titled "Medicare Billing for the Prospective Payment System" that will be held Nov. 16-17 in Arlington, VA. Call (212) 714-1444 for information. ■

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- Discuss the impact your state's certificate-of-need regulations have on quality.
- Explain the importance of the QM department's clear understanding of a study's purpose and scope before it gathers data for a study.
- Be able to list the viewpoints of opponents and proponents of certificate-of-need deregulation.
- Explain how the existence of clinics focused on specific diseases and patients with specific needs can undermine general hospitals.

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