ALASKA LEGISLATURE COMMITTEE FILES 1993-1994 8672
7958 HOUSE LABOR & COMMERCE

The conservative United States Supreme Court has recently upheld a substantial punitive award, in the millions, where the compensatory damages were $19,000 but heavy deterrence was needed. Few other states limit punitive damages. Why should Alaskan juries faced with overwhelming evidence of outrageous conduct be handcuffed?

SWATTING A FLY WITH A HAMMER--MINOR CRIMES
SECTIONS 9-10

Under current law, a person cannot sue for damages received during the commission of a felony. House Bill 292 enlarges the net to include misdemeanors. One outcome:

> A sixteen-year-old collects too many points and has his driver's license suspended. While his parents are away, he drives to the market for some sodas. A dump truck runs a red light and severely injures him. Because he was driving illegally, the boy and his family have no right to recover their loss from the truck driver's insurance company. Now, who pays the enormous medical bills? Most likely, the state treasury.

INCOME TAXES
SECTION 11

This section commands that we take the income taxes which a victim would have paid in the future if uninjured, and give them to -- you guessed it -- the wrongdoer. Congress decided to give injury victims a break by not taxing their recoveries. The bill strips victims of this tax break, and hands it over to wrongdoers.

Most states do not deduct taxes from future lost income awarded by a jury. Figuring out future taxes is highly speculative. The tax code changes, as does the victim's tax status. Will he or she marry? When? How many children? Own a

home? Have an IRA? All these unknowns affect tax liability. The jury is in effect asked to fill out twenty or thirty future tax returns by gazing in a crystal ball.

At a time when everyone is concerned with the expense and delay of lawsuits, does it make sense to add more complexity, court time, and jury aggravation?

AN ADMINISTRATIVE NIGHTMARE: PERIODIC PAYMENTS
SECTIONS 12-13

Under current law, once a lawsuit is over, it's over. The judgment is paid in a lump sum. Future lost wages have been adjusted downward to reflect their early payment. In order to preserve the value of his lost income award, the victim must immediately invest this money, so interest will augment it and permit regular withdrawal to match what his salary would have been. Similarly, the jury has decided on the correct amount to pay the victim for future pain and suffering. The case is closed.

Rather than this straightforward system, the bill would give the wrongdoer the option to pay the victim's future losses on the installment plan. Victim and wrongdoer would be joined for life by ongoing payment obligations. They will drive themselves and the court crazy. Such payments will be expensive to administer, and they won't accomplish anything beyond enriching outside insurance companies.

To set the payment level, the judge will guess the average inflation over the remaining life of the victim. If the judge guesses low, the victim will lose, because the wrongdoer will eventually be able to pay the victim in cheap dollars. A wrong guess can never be fixed, and could wipe a victim out.

The flexibility and discretion a victim currently possesses is eliminated. If the victim has an expensive medical crisis, the timing and amount of payments can't be

adjusted. The bill mechanistically assumes the victim's needs are the same at age twelve and age seventy.

Not all defendants are insured. What if a victim gets a verdict against a reckless uninsured contractor for a million dollars? The judge orders the contractor to pay the victim's damages for the next thirty years. Will the company last half that time? What stops the reckless contractor from pocketing the assets until the company is a shell, and letting it go bankrupt? What would a victim do when faced with the reckless contractor's ultimatum, "Settle for twenty five cents on the dollar or I'll go out of business and you'll get nothing?"

Even with insurance, there is no guarantee the insurer will survive. Many insurance companies become insolvent each year. As of 1987, Executive Life had assets in the billions and the highest possible rating. Now it's bankrupt, with a trail of broken dreams behind it. One hurricane through New Orleans, one California earthquake, could devastate an insurance company. Why leave Alaska's accident victims dependent for life on the solvency of one company?

Who is the big winner here? Out-of-state insurance companies get to control the victim's money. They get to invest it any way they want. It's like an interest free loan. This gift to foreign insurance companies (think they'll cut premiums?) cannot justify this nightmare proposal. No other state has such a law.

COLLATERAL BENEFITS
SECTION 14

Collateral benefits are automatic payments to an injured person from sources such as medical insurance, state medicaid, or workers' compensation benefits. When an injured person sues, he or she makes claim for medical bills or lost wages which might have already been partially paid by insurers. If the jury awards these

damages, the insurers or the State of Alaska get paid back, so there is no double recovery by the victim. This is called subrogation. Subrogation rights are included in virtually all health insurance policies. Reimbursements of workers' compensation and medicaid payments are required by Alaska statutes. The state hires an accounting firm to monitor its medicaid liens.

The bill would cancel these repayments to insurers and the state, and instead reduce the damages payable by wrongdoers. To provide a benefit to proven wrongdoers, the bill penalizes every health and workers' compensation insurance carrier doing business in Alaska, plus raids the state treasury. This is an extremist proposal. One example:

> A state employee is injured. Aetna pays medical bills under Alaska's group health plan. The bill excuses the wrongdoer's duty to reimburse Aetna. But Aetna's rights are unaffected by state law; federal law controls. The employee must repay Aetna out of the jury verdict, even though the verdict does not cover those expenses. End result: the injured employee has no way to recover his past and future medical expenses from Aetna or the wrongdoer.

This section is poorly drafted and is sometimes incomprehensible. It invites litigation over its meaning. It injects significant accounting complications into trials. It allows the jury to know everything about the victim's insurance, but keeps the fact that the wrongdoer has liability coverage strictly confidential! It will increase the cost of health and worker's compensation insurance. It is a misguided, flagrantly unfair imposition on the innocent in favor of the guilty.

TURNING A TRIAL INTO A CIRCUS
SECTIONS 15-16

The boring, technical language of this part of the bill conceals a revolution in how jury trials will work. Under current rules, the parties to a lawsuit each have a

lawyer. The jury listens to everyone, and assigns percentages of fault. For example:

> Victim, hurt in auto accident, sues drunk driver. Drunk driver decides speeder is also at fault, and sues him. The jury hears victim v. drunk, and drunk v. speeder. It finds drunk 50% at fault, speeder 40%, and victim 10%. Speeder has no money. Since 1988, drunk only pays his 50%, no more. Victim alone bears speeder's 40% insolvency. Drunk has benefitted from suing speeder by reducing his own share of fault. However, drunk did bear some risk; if the jury had exonerated speeder, drunk would have to pay speeder's attorney fees.

Obviously, the playing field has tipped dramatically toward defendants since 1988. They can save money by pointing the finger at others, even insolvent others -- but they must first sue those others, and bear some small risk of failure.

The bill changes this balance, by removing the requirement that "drunk" sue "speeder". Now "speeder" is easier pickings, because he is not in court, and has no lawyer. The defense lawyer is going against an "empty chair". Perhaps now the jury will find "speeder" 70% at fault, and drop "drunk" to 20%.

The implications are very troubling. The courtroom can become a circus, with the defendant as ringmaster. Here's just one example:

> Victim is heavily burned in a LP-gas explosion caused by careless. She would have survived, except she is a drinker and a smoker. With weakened liver, heart and lungs, she doesn't have a chance. Victim's husband and kids sue careless. Careless has a smart lawyer, who takes up two months of trial time presenting evidence against the tobacco and liquor industries for failure to warn victim of health hazards. Those empty chairs of course do not fight back. Although such cases have never prevailed in the United States when defended, the jury buys the argument. End result: Careless 40%; Marlboro 30%; Johnnie Walker 30%. Only careless pays; scotch and cigarette don't, because they were never sued. Victim loses 60% of her damages.

The bill gives defendants every incentive to throw long, "Hail Mary" passes by accusing all available persons and entities. The unidentified phantom motorist will become a staple of auto accident cases ("Then I swerved onto the sidewalk to avoid the hit and run driver"). The State of Alaska will be a regular absentee punching bag

("The roadway design was bad, it zigged when it should have zagged"). Reputations will be smeared in court, with no chance to answer ("My colleague Dr. Smith is at fault -- he's a problem drinker and I usually don't let him see my patients, but I made an exception"). The average duration of jury trials will increase, as the truth finding quality of these trials degrades.

Workers will be especially disadvantaged by this change. Now, the workers' compensation law gives employers immunity from civil suit, and no fault can be allocated to them. The bill retains employer immunity, but burdens the worker with the employer's fault. In every case where a worker is hurt, the defense will criticize the employer in absentia, alleging inadequate safety rules, insufficient procedural manuals, lack of inspection and supervision, failure to buy state of the art equipment, to train employees, and the like. Every bit of fault the jury ascribes to the absent and unrepresented employer will directly diminish the injured worker's verdict. The worker will pay for the fault of the employer.

These provisions are the real sleepers of the bill. Wrapped in dry, technical prose is a radical transformation of jury trials, so that much of the trial is about people and companies who are not there. Not only victims will be hurt; taxpayers will pay for longer trials. Individuals and companies will be publicly pilloried and defamed without a chance to respond. Much of the fairness built into our system as we have known it since statehood will be abandoned.

A REWARD FOR STALLING
SECTION 17

Section 17 deals with a partial settlement of a case between a victim and one of several wrongdoers. It is poorly drafted. Under two different interpretations, it is mathematically impossible for a victim who first settles with one wrongdoer before

trial, to e' : recover his full damages at trial. This may not be what the drafters had in mind.

More likely, the intent is to allocate to victims all of the risks, and none of the benefits, of pretrial settlements. Here's how it works:

> *Current law*: "Reasonable" and "hardnose" jointly injure victim. Before trial, "reasonable" pays 40% of the damages. At trial, the jury will still apportion fault to both defendants. If the jury says "reasonable" was 60% at fault, victim forfeits twenty percent of his damages. "Hardnose" never pays more than his 40% fault. The victim's low settlement guess is just his tough luck.
>
> *New law*: Now suppose "reasonable" guessed wrong and paid 60% in settlement. Then the jury finds him 40% at fault. Who gets the benefit? You guessed it -- hardnose, who is 60% at fault but gets a 20% rebate for "reasonable's" overpayment.

A victim can only break even or lose by a partial pretrial settlement. The hardnoses of the world can only break even or win. "Heads I win, tails you lose" is the misguided philosophy here. Settlement is discouraged, and stalling is encouraged. This proposal will increase the cost of litigation, because even parties who want to resolve the claim by settlement will be unable to do so.

MORE REWARD FOR STALLING
SECTIONS 19-20

A wrongdoer pays 10.5% annual interest from the time he receives notice of suit, until the jury decides the case. This is fair, because the wrongdoer has held money currently due the victim for several years, and been free to invest it.

The bill would eliminate most of this duty to pay interest. First, it would exempt most of the judgment, the future part, from any interest at all. Secondly, it would cut the remaining interest to a ridiculously low rate, the federal discount rate plus 1%. That would be 4% in 1993, a very sweet deal for wrongdoers. For example:

> Hardnose Insurance Company knows it must pay three million dollars for a clear fault catastrophic injury. Its nimble defense lawyer says he can stall the case for three years. Old price tag for this tactic: $900,000. New price tag: approximately $70,000. What do you think -- will Hardnose stall, leaving the victim penniless, for the $830,000 reward it can earn by stalling and investing victim's money for three years?

The State of Alaska, after all, charges tax deadbeats a minimum of 11%. At less than 10.5%, insurance companies are given a low interest loan for as long as they can stall the proceedings. It shouldn't be allowed.

WHAT IS A HOSPITAL?
SECTION 24

Should hospitals be allowed to contract out vital patient services they are required by law to provide, to uninsured medical corporations, and wash their hands of the consequences? For example:

> An infant loses both kidneys because of incompetent nursing care in a hospital. He will require weekly blood cleansing (dialysis) for the rest of his life. The hospital denies any responsibility for the substandard care, because it hired Rent-A-Nurse to supply contract nursing services. Rent-A-Nurse was low bidder for the contract because it doesn't bother with insurance. Infant loses, and state medicaid gets stuck for millions.

People go to a hospital because it is an organized, coherent institution, rather than a boarding house for private care providers. If the hospital is immunized for the negligence of routine service contractors, it has no incentive to supervise its emergency room, its radiologists, its anesthesiologists, or its lab. This is poor public policy. The Alaska Supreme Court has ruled that hospitals should be hospitals, and should stand behind the medical care they provide the public, without resort to legal gimmickry. This sensible decision should not be overturned.

AFTERWORD

The drafters of House Bill 292 are nothing if not relentless. Time after time, they seek to disadvantage the innocent victim in favor of the proven wrongdoer. They want to handcuff our discretion when we sit on juries. They want to lock the courthouse doors to many victims, based on random occurrences beyond anyone's control. They want tax breaks, interest free loans, installment plans, insurance benefits, fortuitous immunities -- all for the bad guy, the certified wrongdoer. They want every injured worker to pick up the tab for his or her employer's negligence.

Who are these victims, and why are they deserving of such harsh treatment? They are you and me, and our children, and our children's children. Like innocent victims of crime, they are those among us who will one day suffer a senseless tragedy. They are rich and poor, young and old. They are our most productive workers in our most hazardous jobs. They are us. The valuable rights we treat so cavalierly are <u>our</u> rights. Our jury trials. We are the jurors this bill disdains.

Alaskan legislators have already implemented drastic changes in favor of defendants. Alaskan cities breathe easier, because "deep pocket" liability is no more. The insurance industry is not in crisis. Nationwide, the "tort reform" movement has fizzled out. As the head of Kemper Reinsurance stated, "Tort reform has turned out to be a non-event in terms of its impact on the big picture". We now know from national experience that such measures do not reduce premiums. What we are left with in Alaska is a small group of extremist "tort reformers" who advocate this legislation based on their deep animosity to lawyers and lawsuits, period. Since their bill is technical and complex, legislators may not grasp how drastically it affects the families in their districts.

Legislative Research Agency

Alaska State Legislature

130 Seward Street, Suite 218
Juneau, Alaska 99801-2196

Phone: (907) 465-3991
Fax: (907) 463-3351

January 21, 1994

MEMORANDUM

TO: Rep. Bill Hudson

FROM: Maureen Weeks
Legislative Analyst

RE: **Practice Guidelines in Other States**

You asked us for information about medical practice guidelines in Maine, Vermont and Minnesota.

Maine

As you know, Maine is in the midst of a five-year experiment allowing physicians to join a practice guideline project with the aim of reducing their medical malpractice vulnerability. We are sending you the following articles on the Maine project:

> "Cookbook Care: Maine Limits Liability for Doctors Who Meet Treatment Guidelines," Wall Street Journal, May 3, 1993.
>
> "State of the Art: Maine -- Practice Guidelines May Reduce Liability," State Health Notes, October 5, 1992
>
> State of Maine, "Medical Liability Demonstration Project," Practice Parameters for Anesthesiology, Emergency Medicine, Obstetrics and Gynecology, and Radiology, Board of Registration in Medicine, no date.

We are also sending you detailed information about the Maine project found in presentors' notes used during an "Issues in Medical Liability and Health Care Quality" workshop sponsored by the Agency for Health Care Policy and Research August 3-5, 1992. Presentors Barbara Hastings of the U.S. Public Health Service and Brian Atchison

of the Maine Department of Professional and Financial Regulation describe the program's goals, schedule and requirements. You may find some of this material useful.

We previously sent you a copy of the Maine law: Medical Liability Demonstration Project Title 24 Section 2971. Frank Stread (pron. "strood") at 207-622-3374 can give you more information about the project.

Vermont

Practice guidelines are voluntary in Vermont, according to Herb Olson, health care specialist with the Vermont Legislative Council. Title 12 Section 7003 of Vermont Statutes Annotated (attached) states that established guidelines "shall be" admissible as evidence of whether a provider has met the appropriate standard of care. Mr. Olson can be contacted at 802-828-2231.

Minnesota

The Minnesota legislature set up the machinery for voluntary practice guidelines in the 1992 "Health Reform Law," according to Ginny Weslowski of the state health department (612-282-6339). The Minnesota law follows the concept pioneered in Maine. The health department is currently deciding whether Minnesota should draw up its own guidelines or use nationally recognized guidelines, such as those written by the U.S. Public Health's Agency for Health Care Policy and Research, which uses expert panels to develop clinical guidelines for a myriad of medical situations (301-227-8364).

Overviews

We are also sending you two overview articles you might find useful. They are:

J. Kosterlitz, "Cookbook Medicine," National Journal, March 9, 1991, p. 574.

S. Findlay, "Medicine by the Book," U.S. News and World Report, July 6, 1992, p. 68.

I hope this information is useful to you. If we can be of further help, do not hesitate to call.

MAINE

User Liaison Program
Center for Research Dissemination and Liaison
Agency for Health Care Policy and Research
U.S. Public Health Service

Presents

Issues in Medical Liability and Health Care Quality

A Workshop For State Legislators and Senior Health Officials

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Health Systems Research, Inc.

Lafayette Hotel
Boston, Massachusetts
August 3-5, 1992

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Session 8.

MEDICAL LIABILITY AND PRACTICE GUIDELINES: THE MAINE EXPERIMENT

TIME: 1:30 - 3:00 p.m., Tuesday, August 4

PRESENTER:

Kathleen Hastings, R.N., J.D.
Director, Legal Medicine Program
Office of the Administrator
Agency for Health Care Policy and Research
U.S. Public Health Service

Brian Atchinson, J.D.
Legal Counsel
Maine Department of Professional and Financial Regulation

DESCRIPTION: One of the more innovative approaches being taken by an individual state to address the medical liability problem is the State of Maine's effort to establish medical practice guidelines that can be used in medical liability disputes. In this session a representative from the State of Maine describes the factors that led to the development of this initiative and provides up-to-date information on its implementation.

Kathleen Hastings

TERMINOLOGY
(Alphabet Soup)

"PRACTICE GUIDELINES" may mean different things to clinicians, patients, purchasers, and attorneys.

The same person may even use the term differently in different contexts.

Other terms are often used interchangeably, which have similar (but sometimes slightly distinct) meanings.

OTHER FREQUENTLY USED TERMS

- practice parameters
- practice policies
- clinical indicators
- protocols
- norms
- algorhythms
- decision trees
- critical pathways
- standardized specifications for care

WHAT ARE PRACTICE GUIDELINES?

"I typed in your description of the symptoms ...

The computer says you have Dutch Elm Disease."

DICTIONARY DEFINITIONS

To guide = to direct the course of, and
to lead in a course of action
or the direction of events

Guideline = any guide or indication of a future
course of action

PRACTICE GUIDELINES

Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.

IOM, 1990

WHY GUIDELINES?

- variations in clinical practice patterns
- uncertainty of quality, effectiveness, appropriateness
- "explosion" of scientific knowledge
- rapid growth in medical technology
- much information that could improve health care decision-making is not available in formats which are readily useable by clinicians and patients

WHAT WILL GUIDELINES DO?

- *convert* science-based knowledge to clinical action
- *clarify* health care choices for the consumer
- *improve* the scientific basis for quality improvement strategies

Brian Atchinson

MEDICAL LIABILITY DEMONSTRATION PROJECT

GOALS

TO ESTABLISH PRACTICE PARAMETERS AND RISK MANAGEMENT PROTOCOLS CONSISTENT WITH APPROPRIATE STANDARDS OF CARE, DESIGNED TO:

- AVOID MALPRACTICE CLAIMS;
- IDENTIFY AND QUANTIFY THE PRACTICE OF DEFENSIVE MEDICINE; AND
- REDUCE THE PRACTICE AND COST OF DEFENSIVE MEDICINE

MEDICAL LIABILITY DEMONSTRATION PROJECT
PARTICIPATING SPECIALTIES

- ANESTHESIA
- OBSTETRICS AND GYNECOLOGY
- EMERGENCY MEDICINE
- RADIOLOGY

LIABILITY CLAIMS TO BE TRACKED 1/1/92 - 12/31/96

PROJECT SCHEDULE

1. EACH OF THE MEDICAL SPECIALTY ADVISORY COMMITTEES DEVELOPED PRACTICE PARAMETERS AND RISK MANAGEMENT PROTOCOLS AND PROVIDED A REPORT ON THOSE ADOPTED BY THE BRM AND BEOR BY MARCH 1, 1991 TO THE JUDICIARY COMMITTEE AND LEGISLATIVE COUNCIL.

2. PRIOR TO NOVEMBER 1, 1991 ANY PHYSICIAN PRACTICING IN ONE OF THE DESIGNATED MEDICAL SPECIALTY AREAS WAS REQUIRED TO FILE NOTICE WITH THE BRM OR BOER, INDICATING WHETHER THEY ELECT TO PARTICIPATE IN PROJECT.

3. THE MEDICAL LIABILITY DEMONSTRATION PROJECT ESTABLISHED AS OF JANUARY 1, 1992.

4. BY JANUARY 1, 1992, THE BRM RECEIVED A REPORT SETTING FORTH THE METHODOLOGY DEVELOPED BY THE ECONOMIC ADVISORY COMMITTEE FOR EVALUATING THE PROJECT'S EFFECT ON THE COST, UTILIZATION, AND PRACTICE OF DEFENSIVE MEDICINE.

5. BY DECEMBER 1, 1997, THE BOI AND BRM SHALL REPORT PROJECT RESULTS TO THE GOVERNOR, THE LEGISLATIVE COMMITTEES FOR INSURANCE AND JUDICIARY MATTERS, AND THE LEGISLATIVE COUNCIL.

MEDICAL LIABILITY DEMONSTRATION PROJECT
OBSTETRICS AND GYNECOLOGY PRACTICE PARAMETERS

CONTENTS:

PHYSICIAN PARTICIPATION LEVELS

NOVEMBER 1, 1991

50% MINIMUM PARTICIPATION REQUIRED FOR EACH SPECIALTY

375 DOCTORS ENROLLED

- 59 ANESTHESIOLOGISTS (53%)
- 106 EMERGENCY MEDICINE SPECIALISTS (68%)
- 58 RADIOLOGISTS (60%)
- 152 OBSTETRICIANS AND GYNECOLOGISTS (57%)

RECENT STATUTORY CHANGES

- OPEN ENROLLMENT NOW PERMITTED IN DEMO PROJECT FOR PHYSICIANS NOT ENROLLING BY NOVEMBER 1, 1991 (CANNOT REJOIN AFTER WITHDRAWAL)

- AFFIRMATIVE DEFENSE OF COMPLIANCE WITH PARAMETERS AND PROTOCOLS TO BE ALLOWED AT PRELITIGATION SCREENING PANELS (MANDATORY ADR TRIBUNAL)

MAINE TORT AND HEALTH CARE REFORM INITIATIVES

- RURAL MEDICAL ACCESS PROGRAM (1990)
- COLLATERAL SOURCE LAW (1990)
- MANDATORY PRELITIGATION SCREENING PANELS (1987)
- STRUCTURED MALPRACTICE AWARDS AND PERIODIC PAYMENTS (1985)
- CONTINGENT FEE LIMITATION ON ATTORNEYS IN MALPRACTICE ACTIONS (1985)
- MAINE MEDICAL ASSESSMENT PROGRAM (1981)

MAINE HEALTH INSURANCE INITIATIVES

- HIGH RISK POOL
- PRE-EXISTING CONDITION PROHIBITION
- GUARANTEED ISSUANCE AND RENEWABILITY - SMALL GROUP
- BARE BONES/REDUCED MANDATE SMALL GROUP INSURANCE OPTION
- COMMUNITY RATING (± 50% REDUCES TO 0% OVER 5 YEARS)

John R. McKernan, Jr.
Governor

Brian K. Atchinson
Superintendent

DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION
BUREAU OF INSURANCE
(207) 582-8707
Telecopier (207) 582-8716

DRAFT

PROPOSED RULE CHAPTER 680
MEDICAL LIABILITY DEMONSTRATION PROJECT

Section 1 - Purpose

The purpose of this Rule is to establish the format that any insurance company providing professional malpractice insurance or any other form of liability insurance to any physician practicing in the medical specialty areas described in 24 M.R.S.A. §2972(1) or to any hospital in which that practice has taken place shall utilize in reporting to the Bureau of Insurance in order to comply with the Medical Liability Demonstration Project.

Section 2 - Authority

This Rule is promulgated pursuant to 24 M.R.S.A. §2978(5), and 24-A M.R.S.A. §212.

Section 3 - Definitions

For the purposes of this rule, the following terms have the following meanings:

A. "Insurer" means any insurer authorized to transact insurance in Maine.

B. "Superintendent" means the Superintendent of Insurance.

C. "Policy year data" is based upon the year in which the policy giving rise to exposures, earned premiums, claims and losses is effective.

D. "Claim" means a demand which seeks damages or the insured's report of an injury or death which will likely result in such demand.

E. "Date of claim" means the date that the claim is reported to the insurer.

F. "Date of incident" means the date the event occurred.

G. "Open claim" means a claim which has possible pending litigation and/or legal expense.

H. "Closed claim" meansa claim with respect to which all indemnity and/or legal expense has been paid or a claim which has been dismissed by a court of

competent jurisdiction.

I. "Subrogation" is defined as when the insurer pursues any rights the insured may have against a third person or party liable for a loss paid by the insurer.

Section 4 - Reports

A. Claims Information

1. A report of each claim made alleging malpractice during the 5-year period ending December 31, 1991, involving any physician practicing in a medical specialty area described in 24 M.R.S.A. §2972(1) must be filed with the Superintendent by each insurer no later than May 1, 1993. Reports with respect to all open claims must be updated as of May 1 of each year.

2. A report of each claim made alleging malpractice on or after January 1, 1992 and before January 1, 1997, involving any physician practicing in a medical specialty area described in 24 M.R.S.A. §2972(1) must be filed with the Superintendent by each insurer on March 1 of the year following the reported policy year. Reports with respect to all open claims must be updated as of May 1 of each year.

Each report must include the following by policy year and by specialty:

1) the insurance company name;
2) a description of the report as number A1 or A2 dependent on which of the subsections above the report relates to;
3) the date of report;
4) the name of insured;
5) the physicians Maine license # as issued by the Board of Registration of Medicine;
6) the policy number;
7) the physicians date of birth;
8) classification of risk according to the classification codes utilized by the insurer in their rate filings;
9) medical specialty area of the physician (EM, RAD, ANTH, OB/GYN);
10) the claim number;
11) the date of claim;
12) the date of incident;
13) the status of claim (open or closed);
14) the valuation date of claim;
15) the description of event giving rise to claim;
16) the location (hospital or physicians office, address);

TREET JOURNAL.

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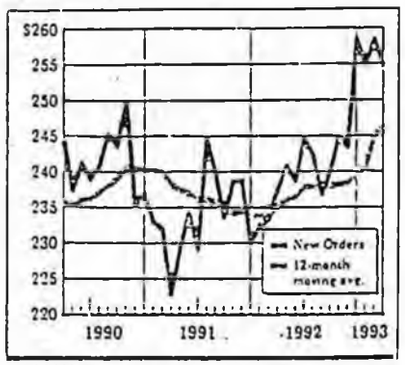

NEW ORDERS reported by manufacturers in March fell to a seasonally adjusted $254.53 billion from a revised $258.38 billion in February, the Commerce Department reports. The 12-month moving average rose to $246.46 billion in March from a revised $245.05 billion in February. (Article on page A2).

Maybe Their Statue Of Liberty Will Grip A Big Slice of Pizza

* * *

Free of Socialism but Short Of Mozzarella, East Europe Makes Pies Any Way It Can

By BARRY NEWMAN
Staff Reporter of THE WALL STREET JOURNAL

WARSAW — A fast-food stand on Chmielna Street encapsulates the whole expanse of Eastern Europe's post-Communist pizzafication.

Through its window, Grazyna Kalisz dispenses two dishes: *zapiekanki*, Polish communism's bravest attempt to simulate the pizza pie; and the *Delicja*, a leading-edge, prepackaged brand of pizza, mass produced by Polish capitalism.

A zapiekanki is half a long roll with melted cheese and mushroom flecks on top. Ms. Kalisz makes them on the spot. The Delicja is round, sprinkled with ham and cheese, and comes from the factory frozen in a plastic bag. Ms. Kalisz thaws them out in her microwave.

A middle-aged woman orders a zapiekanki. Ms. Kalisz squirts a squiggle of ketchup on one and serves it in exchange for 45 cents. "If you are hungry, you eat," the woman says, taking a bite. Then a

The Outlook

Choices for Shrinking Japan's Trade Surplus

WASHINGTON

One of these days, President Clinton's economists are going to give him a multiple choice test that goes like this:

The best way to shrink Japan's huge trade surplus is: (a) get Japan to stimulate its economy and lift the value of the yen, or (b) get Japan to set firm targets for imports of particular U.S. goods.

Label the first the Lawrence Summers option, after the Treasury undersecretary. Label the second the Laura D'Andrea Tyson option, after the he d of the Council of Economic Advisers. As he often does, the president will want to pick option (c), both of the above.

Of course, the U.S. can and will lean on Japan both to strengthen its economy—so it will take in more imports—and to promise to buy more from crucial U.S. industries. But not everything can be at the top of Mr. Clinton's wish list. It is difficult, perhaps counterproductive, to deluge Japan with demands — aid Russia, increase government spending, buy more auto parts—and tell them that each is the No. 1 priority.

In a revealing comment the other day, Mr. Clinton ticked off his remedies for Japan's trade surplus — all of them: "Number one, the appreciation of the Japanese yen. Number two, the stimulus program which the [Japanese] prime minister has talked about. Number three, a breathtaking increase in productivity and quality by American manufacturers . . . and, number four, a commitment to focus sector-by-sector" on getting U.S. goods into Japan.

That last point was an eye-popper. While the U.S. traditionally has pushed for open markets, it has shied away—with occasional exceptions — from pre-empting market forces and using government negotiations to determine how much of any product a foreign country should buy.

Each side in the internal tug of war took his comments as a sign that it was winning. But the reality is that no one is. Mr. Clinton, who promised to focus on the economy, has spent far more time on Russia, an economic wreck, than on Japan, a true superpower. Mr. Clinton's advisers barely managed to figure out what he should tell Prime Minister Kiichi Miyazawa before he showed up at the White House.

The disagreements aren't about who

Cookbook Care

Maine Limits Liability For Doctors Who Meet Treatment Guidelines

Novel Test Seeks to Eliminate Medical Procedures Done To Curb Legal Exposure

Model for Clinton Task Force?

By EDWARD FELSENTHAL
Staff Reporter of THE WALL STREET JOURNAL

LEWISTON, Maine — Doctors are practicing cookbook medicine here these days, and they're complaining remarkably little about it.

In the past two years, the state has issued 22 sets of checklists, which guide doctors on what to do for patients with particular conditions. A checklist for emergency-room doctors instructs them not to bother giving neck X-rays, as they almost always did in the past, for certain trauma patients who don't have neck pain. A list for obstetricians sets out eight steps they should take before performing some Caesarean deliveries.

Doctors ordinarily resist such micromanagement of their craft, but here they have good reason not to. In return for following the checklists, physicians get something at the top of their wish list: protection in malpractice lawsuits.

At a time when the Clinton administration is seriously considering a variety of medical-malpractice reforms as part of its health-care package, Maine's experience is instructive. For one thing, the Maine physicians' complaisance about the checklists may be a sign that doctors are coming to grips with changes they once opposed but now view as inevitable. And it illustrates how malpractice relief can serve as a political chip to enlist physician support for controversial changes.

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Of Mozzarella, East Europe Makes Pies Any Way It Can

By Barry Newman
Staff Reporter of The Wall Street Journal

WARSAW — A fast-food stand on Chmielna Street encapsulates the whole expanse of Eastern Europe's post-Communist pizzafication.

Through its window, Grazyna Kalisz dispenses two dishes: *zapiekanki*, Polish communism's bravest attempt to simulate the pizza pie; and the *Delicja*, a leading-edge, prepackaged brand of pizza, mass produced by Polish capitalism.

A zapiekanki is half a long roll with melted cheese and mushroom flecks on top. Ms. Kalisz makes them on the spot. The Delicja is round, sprinkled with ham and cheese, and comes from the factory frozen in a plastic bag. Ms. Kalisz thaws them out in her microwave.

A middle-aged woman orders a zapiekanki. Ms. Kalisz squirts a squiggle of ketchup on one and serves it in exchange for 45 cents. "If you are hungry, you eat," the woman says, taking a bite. Then a teenage boy walks up and orders a Delicja. Ms. Kalisz cooks one, adds a thick glop of ketchup, and accepts 65 cents. "I used to buy zapiekanki," the boy says. "But pizza is more food."

Free to Feast

So it is that the hand-to-mouth habits of the past are evolving into the face-stuffing techniques of the future. For the masses who withstood the menus of gastronomic centralism, pizza has become a symbol of intestinal liberation. Yet the road from zapiekanki to Delicja is paved with hardship and controversy: the sauce shortage, the mozzarella question, the spice barrier — and the issue of fruit. Stages of pizza progress are leading indicators in Eastern Europe. Westernization seems to advance in step with the choice of toppings.

Americans of deep-dish persuasion are both the slickest and the sorriest of the East's pizza missionaries. The Budapest Pizza Hut, with all the mozzarella PepsiCo can buy, doesn't just sell its usual amalgam of bread and goo, it sells Hollywood. Movie-star murals line the walls. Dummies in evening dress loll at cafe tables. The place is more Stork Club than family restaurant.

But 600 miles from Budapest—and 6,000 from Chicago, where both she and the deep-dish were born—Rita Dapkus lives in mozzarella pre-history. She has opened a take-out pizza kitchen in a factory at the edge of Vilnius, in Lithuania. On the table in front of her lies a slab of bread apparently covered with melted plastic.

Dreaming of Deep-Dish

"I'm not having any," says Ms. Dapkus. "I can't look at it any more." The plastic is a Soviet variation on Velveeta, and the red ooze beneath it a mix of scarce tomatoes and surplus apples. Ms. Dapkus eyes it morosely. "I can't make deep-dish without mozzarella. I'd love to make deep dish."

Pizza is her second Lithuanian career. Ms. Dapkus first ran the press office of the Sajudis liberation movement, sweating

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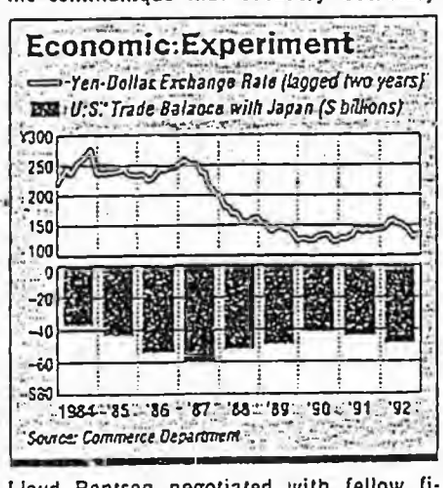
> The disagreements aren't about who is friendlier to Japan; both camps are frustrated by recent dealings with the Japanese. The argument is about the best way to narrow the U.S. trade deficit with Japan, which was $50 billion last year. The deficit with the rest of the world was $46 billion.

The Summers option, widely supported by economists, draws on lessons of the 1980s. As the dollar fell and the yen rose, the trade gap with Japan shrank with the two-year lag that textbooks predict. "The conventional wisdom has performed acceptably well, indeed better than we might have expected," Massachusetts Institute of Technology economist Paul Krugman says.

The prescription is the one expressed in the communique that Treasury Secretary



Lloyd Bentsen negotiated with fellow finance ministers last week. Japan should increase government spending or cut taxes to prod its economy; that will increase Japanese demand for imported goods and push up the value of the yen, making Japanese goods less attractive in the U.S. The screams from Japan as the yen has risen show how potent the exchange-rate medicine can be. The roughly 10% increase in the yen so far this year amounts to a 10% tax on all Japanese products sold in the U.S. Such an approach, the argument goes, would far surpass what might be accomplished by

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Under the Maine program, if it is uncontested that a doctor adhered to the apropriate checklists, any suit against him can be dismissed before trial. Otherwise, the patient can win only by proving that the doctor unreasonably deviated from the guidelines. Doctors hope that the program will reduce the incentive to sue them and lead to lower malpractice-insurance rates, though so far that hasn't happened.

Many physicians attack checklists as paint-by-numbers medicine that ignores the idiosyncrasies of patients' conditions. Yet policy planners are pushing the idea harder than ever. They argue that checklists, formally called parameters or practice guidelines, will deter doctors from performing unnecessary procedures just to protect themselves against lawsuits. Such measures, called defensive medicine, are variously estimated to cost $4 billion to $25 billion a year. Guidelines, subject to periodic revisions, may also serve to keep doctors better informed about changing medical standards.

Overwhelming Support

Government agencies and physicians' groups have published hundreds of recommended guidelines in recent years. And President Clinton, whose health-care task force is to issue its proposals this month, has said that he supports establishing more practice guidelines and using them to try to cut costs.

Maine has taken checklists an unprecedented step forward by writing them into law and linking them to malpractice relief. Fashioned as a five-year experiment, the law applies to four specialties: obstetrics and gynecology, radiology, emergency medicine and anesthesiology. Physician-dominated committees wrote the guidelines, which were to take effect only if more than half the doctors in each specialty chose to participate in the experiment. Ultimately, 80% of the eligible physicians signed on.

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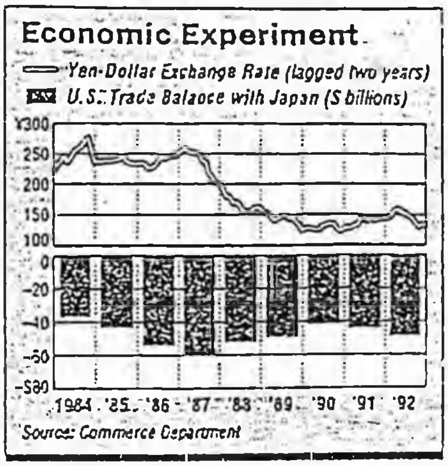

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Ms. Tyson counters that the Japanese trade surplus is "highly resistant to macroeconomic solutions." A 10% rise in the value of the yen will reduce the Japanese surplus with the U.S. by about $5 billion after two years, she figures. Using standard computer models of the economy, she says that to increase U.S. exports to Japan by $25 billion, the Japanese economy would have to grow by 50%, a very unlikely scenario. She concludes that the U.S. must supplement the textbook economic remedy with results-oriented negotiations to force Japan to buy more U.S. products, particularly in high-technology industries.

Ms. Tyson is moderate compared with some administration officials. Mickey Kantor, the pugnacious U.S. trade representative, and Ronald Brown's Commerce Department — with its traditional institutional bent toward helping particular U.S. industries—want Mr. Clinton to wrest industry-specific import commitments out of the reluctant Japanese. Mr. Clinton's comments suggest he leans in their direction.

So, while it pursues the Summers option, the administration also wants to reach agreement with Japan on a few key industries to target before Mr. Clinton goes to Tokyo in July. Until Mr. Clinton picks (a) or (b), U.S. policy will be option (c).

—David Wessel

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Already, the checklists may be helping to break some entrenched, and costly, habits. Emergency-room officials at Maine Medical Center estimate that about 50% of victims of falls and car accidents now get $170 neck X-rays, compared with about 95% of such patients before the experiment began. Anesthesiologists say they are doing fewer blood tests and chest X-rays before surgery. And radiologists cite the guidelines as one reason they no longer require that many patients stay overnight in the hospital after certain blood-vessel X-rays.

Known Recipes

Just as experienced chefs only rarely refer to their cookbooks, most doctors don't regularly need to pull out the guidelines. Indeed, some of the checklists are simply restatements of procedures that are already standard practice for most doctors, particularly in big hospitals with extensive internal guidelines. "We were already following [these guidelines] and more," says Phillip Stubblefield, chief of obstetrics at Maine Medical Center.

But the guidelines have changed the calculus of doctors' decisions about some treatments. Waterville obstetrician Margaret Griffin now does an extra test before performing hysterectomies on women with abnormal levels of uterine bleeding. The guidelines say to make sure the bleeding isn't caused by polyps in the uterus, which can be treated without major surgery. Previously, Dr. Griffin didn't do that test

Please Turn to Page A5, Column 1

Cookbook Care: To Curb Medical Tests, Maine Gives Physicians a Legal Shield if They Follow Guidelines

Continued From First Page

because it only rarely shows polyps triggering the bleeding, she says.

Portland anesthesiologist Katherine Pope so disagrees with one guideline — a provision calling for pre-surgical anemia tests on babies under six months old — that she refuses to follow it. But many other doctors say they fully comply with all the checklist provisions in order to get as much liability protection as possible. Emergency physician Christopher Clark says he won't deviate at all from a checklist on transferring patients from one hospital's emergency room to another hospital. The checklist, which mirrors federal regulations on transfers, spells out 11 requirements for transfers, such as ensuring that the condition of the patient to be transferred has stabilized and sending the patient's records to the other hospital. Beside each requirement is a space where doctors can indicate it has been met.

The transfer checklist "helps me to stay organized," says Dr. Clark, who works in four central Maine emergency rooms. "The nurse will put the list right under my nose and say the patient can't go until I sign" the checklist to indicate that all the conditions have been met. Dr. Clark also has made the guideline on when to give neck X-rays a part of his permanent equipment. "I carry it with me all the time" in my bag, he says.

Some doctors have found unexpected uses for the checklists. Dr. Griffin, the Waterville obstetrician, sometimes shows them to patients when she wants to influence their decisions about whether to get a particular treatment. She used a guideline on herpes, for instance, to convince a pregnant woman with a herpes virus that she didn't need weekly cervical tests because it wasn't currently active. Although the guidelines say the tests aren't necessary for women with inactive viruses, they were once routine, and some patients still come in expecting them.

Also, Dr. Griffin has attached copies of checklists to patients' charts so she can mark them when she completes each requirement. "It's a nice way of making sure that you've done all the things you're supposed to do," she says.

How It Began

The experiment was the brainchild of a coalition of businesspeople and interest groups formed to present legislators with a plan for health-care reform. Representatives of the state medical association, which lobbies for doctors, urged the group to consider malpractice reforms. But others in the coalition opposed limiting patients' right to sue without greater assurances that doctors would adhere to high standards of care. The resulting compromise was the plan for guidelines.

To gain the medical association's support, coalition members agreed that plain-

But opposition didn't die with the legislature's vote. Lawyers who typically defend doctors, and who hadn't objected to the bill in the legislature, unexpectedly began warning doctors that the checklists would do them more harm than good in court. Despite the language of the bill, they contended, creative plaintiffs' lawyers would find a way to introduce the lists against doctors. And they said checklists would make it hard to explain to juries why doctors' decisions sometimes deviate from the stated guidelines.

The lawyers made their case in a mass mailing that the state's largest malpractice insurer sent out as doctors were deciding whether to join the experiment. Their timing infuriated plan supporters. "A classic example of the fox guarding the henhouse," Dr. Stubblefield calls it. "If there are fewer malpractice cases, we don't need so many lawyers."

The supporters fought back, lobbying colleagues and soliciting contrary opinions from defense lawyers who favored the experiment. On the day before the sign-up deadline, Pamela Bensen, a physician who helped write the emergency medicine guidelines, spent 10 hours on the phone pitching the plan to doctors who were on the fence. Such collegial pressure worked. About 90% of radiologists, 83% of obstetricians, 67% of anesthesiologists and 76% of emergency doctors signed up.

Potential Imitators

Other states are following Maine's lead. Legislatures in Vermont, Minnesota and Florida have called for the development of guidelines as part of their health-care reform plans. Similar legislation is pending in Pennsylvania. U.S. Sen. William Cohen of Maine has introduced a bill in Congress to set up a federal checklist program. And health reformers in almost every state have asked Maine officials to share their findings. As "the rest of the world has woken up to the uses of

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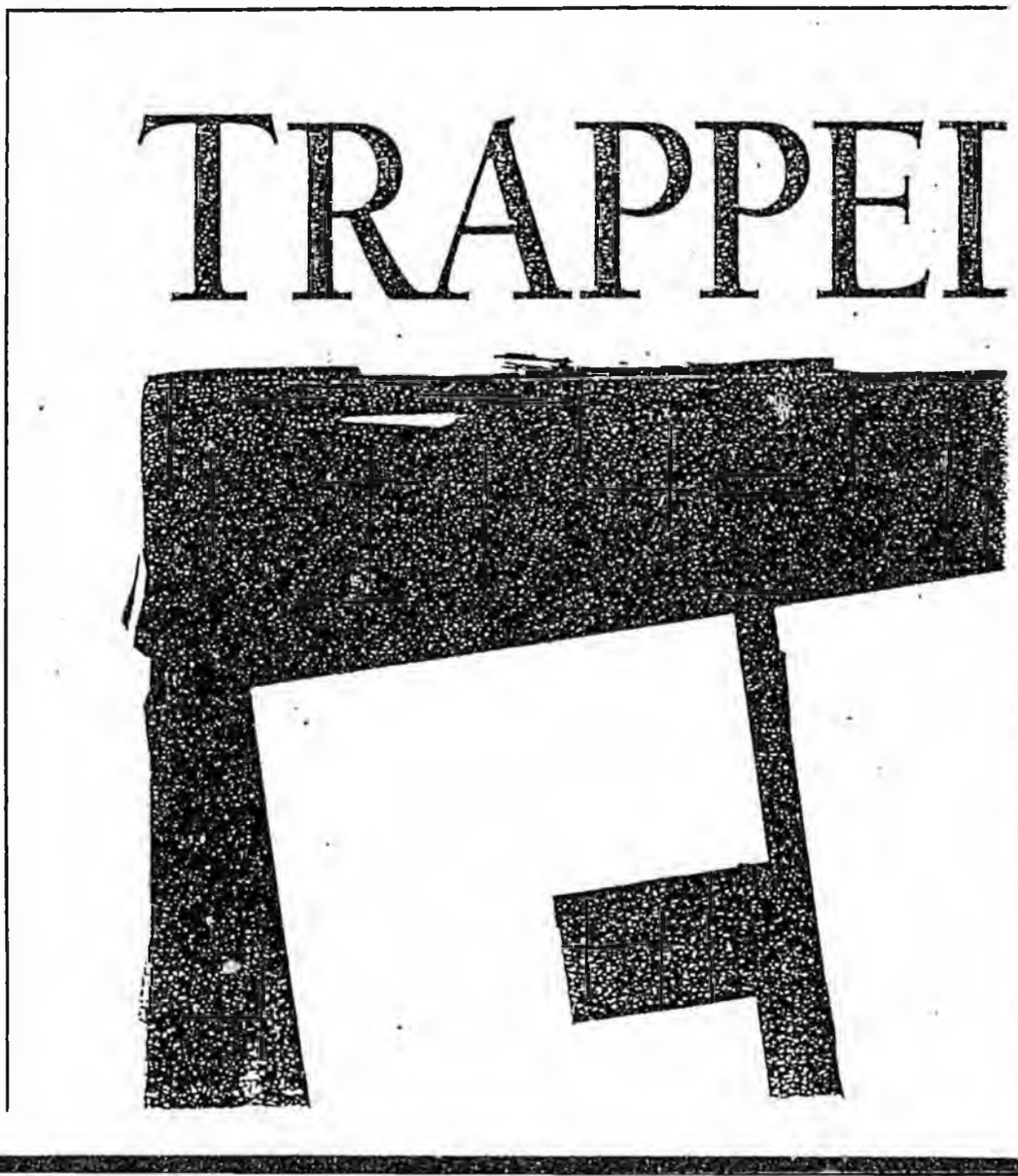

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To gain the medical association's support, coalition members agreed that plaintiffs wouldn't be able to cite noncompliance with the guidelines as evidence of negligence, allaying doctors' great fear that the guidelines would boomerang against them in court. And the coalition agreed doctors wouldn't be forced to participate. It also called for local physicians, rather than academics or policy makers, to design the guidelines. "It's not like some ivory-tower physician at some medical center in New York City telling [us] what to do," says David Johnson, a Lewiston emergency physician.

The doctors also hoped that by supporting the checklist plan, they could win sweeping malpractice change, such as caps on jury awards for emotional distress and a provision reducing malpractice awards by the compensation plaintiffs get from insurance and other sources. We knew that "legislatures aren't really willing to give [malpractice reform] carte blanche," says John Makin, an obstetrician who helped write the guidelines.

Trial lawyers mustered the plan's primary opposition in the legislature, contending that it violated plaintiffs' rights by barring them from using the checklists against doctors. But after weeks of negotiating, the legislature approved the experiment at 4:30 a.m. the last night of its 1990 session. The law included much of what the physicians had asked for, including the provision subtracting insurance payments from malpractice awards and a program to help rural obstetricians pay their malpractice premiums. Caps on damages, one of the proposals also under consideration by the Clinton staffers, weren't approved.

Weak Economic Data Give Rise to Questions Concerning Slowdown

Continued From Page A2

income growth picks up more steam.

Factory orders were dragged down mainly by a 35.9% plunge in aircraft orders — a category that is quite volatile. Orders for instruments also declined, while orders for industrial machinery and

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Those who put it in place warn, though, that it may not be reproduced easily elsewhere. The plan's success, Maine officials say, was fostered in part by some factors peculiar to their state. For one, its population of 1.2 million includes fewer than 170 doctors in each of the four specialties. "You can [practically] get those people in a room together" to forge a consensus, says Gordon Smith, a medical association lobbyist who helped write the checklist law.

Oddly, Maine's harsh winter also aided the program. A blizzard kept would-be opponents away from a public hearing on whether the committees' drafts of the checklists should be adopted. And Maine doctors say the idea of taking part in a path-breaking experiment, even if it flopped, appealed to their sense of adventure. "The stakes aren't very high" in Maine, says Donald McDowell, president of Maine Medical Center. "It affects relatively few people if we screw up."

The experiment's backers concede that it could go awry in several ways. First, state officials doubt that many test cases will emerge that directly involve treatments in the checklists. No such case has yet been filed, raising concerns about whether the state will be able to gauge the plan's legal merits. Until insurers can find out whether the law truly protects doctors from malpractice verdicts, rates aren't expected to budge.

Patients' complaints could also derail the plan. As with any reform aimed at reining in unnecessary care, some patients worry that their treatment will be compromised. Jeanine Kivus, a mother of five sons in Lewiston, says one son wasn't given a neck X-ray when he was taken to an emergency room after a mountain-bike accident shortly after the experiment began. Four days later, he nearly collapsed, Ms. Kivus says, prompting an X-ray that showed he had broken his neck in the accident. "If there is any question of a possible back or neck injury, I think it should be explored," she says. "I don't want one of my sons to be one of the ones that slips through" the cracks.

In addition, the program may not succeed in cutting much fat from the state's health tab. The number of Caesarean sections performed in Maine continues to increase slightly, for example, leaving some doctors skeptical about whether the experiment will lower obstetric costs. Checklists that require extra treatments, such as the polyps test for hysterectomy candidates, will add some new costs. To comply with checklist requirements, some doctors also have had to buy additional equipment for administering anesthesia and monitoring fetuses.

But the program is, after all, only an experiment. Despite pitfalls, it is a creative new idea that "deserves evaluation," argues Marc Roberts, a Harvard professor of health policy. Even some national physician groups wary of state-issued checklists have said that the idea deserves to be better evaluated. A few of them, including the American Medical Association, encouraged Maine doctors to participate in the experiment.

And whatever the program's success in reducing costs, it is already helping mollify doctors, who until now have felt squeezed by pressures to cut back on treatments without more protection from lawsuits. "I feel better that the parameters are there," says Dr. Clark, the emergency physician. "When I don't do [an X-ray] . . . I feel safer."

State of the Art: Maine

Practice Guidelines May Reduce Liability

In MAINE, a five-year experiment to reduce medical liability now offers doctors a way to lower malpractice premiums. The project has introduced practice protocols aimed at reducing physicians' dependence on defensive medicine. Authorized by legislators in literally their last act of the 1990 session, the new guidelines are an effort by doctors and lay people alike to select standards for care ranging from preadmission testing to caesarean section procedures during delivery.

For physicians who elect to join the project, the protocols provide a defense against malpractice actions by patients, but may not be the basis for a suit. (This protection is known as an "affirmative defense.") Some doctors maintain that malpractice suits have little to do with the actual quality of care provided, and several studies bear these providers out.

To prevent such suits, the project uses explicit standards to link treatment to liability, explained Gordon Smith, counsel for the Maine Medical Association (MMA). John Makin, a physician and chairman of the committee that developed the obstetrics and gynecology guidelines agreed: "It eliminates second guessing by outside experts."

In developing the protocols, the state's medical and osteopathic boards jointly convened specialty panels to propose and adopt standards by rule. Four specialty groups—obstetrics and gynecology, anesthesiology, radiology and emergency medicine—assembled 22 practice protocols. Health care consumers also participated in the panels, and patient-physician communication plays a role in every standard.

The groups' efforts were directed at procedures or conditions the members identified as being likely to promote defensive medicine practices or lead to tort liability. Rather than drafting the guidelines from scratch, the groups looked at national practice standards and adapted them to Maine.

According to Dan Meyer, a member of the evaluation study group, this process led to choosing common practices rather than best practice standards that might be less familiar to all practitioners. New standards may be adopted by the medical and osteopathic boards as the experiment progresses.

As each group chose guidelines for its specialty area, practicing physicians

> ***" [The protocols] eliminate second guessing by outside experts."***

were alerted to the proposed standards. Specialists who chose to join the experiment were required to declare their intent to do so by late last fall. For a specialty to become eligible for the project's tort protections, half of the doctors in the specialty were required to participate. Specialties that were unable to meet this benchmark would have been dropped from the experiment.

Unlike VERMONT and MINNESOTA, which now require the use of practice parameters, the success of Maine's project hinges on voluntary participation. According to Meyer, this approach offered physicians a greater degree of involvement early on in the process.

As a result, doctors who supported the guidelines worked hard to bring their colleagues on board as well. When liability protection began on January 1, 1992 almost 90 percent of the eligible specialists had signed on.

Though support for the experiment has solidified, the legislation authorizing it met with some resistance. Sen. Paul Gauvreau, a key sponsor, noted that the law passed after "robust legal debate" and added he hopes the inevitable test case comes early. Trial lawyers opposed the law as possibly unconstitutional, and the state's largest malpractice insurer warned its subscribers of the project's uncertain legal ramifications.

In response, the state's specialty societies, as well as national specialty colleges, worked to counteract the insurer's warnings. That the guidelines themselves were based on existing practice parameters aided their cause. "[The groups] put known standards into law, doing away with the battle of experts," MMA's Smith argued.

Though a full evaluation is several years in the offing, observers expect that practice changes, such as fewer orders for neck X-rays, may be evident before the year is out. Both the U.S. General Accounting Office and the Rand Corporation have expressed interest evaluating the project at some future date.

In addition to protecting physicians, the protocols offer hospitals a basis for updating their equipment and practices. Small, rural hospitals, say many observers, stand to gain the most.

"So many [doctors in these hospitals] cry wolf, that risk managers get blase," commented Richard Flowerdew, an anesthesiologist and chairman of that specialty's protocol group. The guidelines, he argued, may help staff physicians substantiate their requests. • KL

Maine

02-373 BOARD OF REGISTRATION IN MEDICINE

Chapter 20: Medical Liability Demonstration Project - Anesthesiology Specialty Practice Parameters and Risk Management Protocols.

SUMMARY: This chapter implements 24 M.R.S.A. c. 21, sub-c IX by defining the eligibility requirements for enrollment of Maine licensed allopathic physicians practicing in the medical specialty of Anesthesiology in the Medical Liability Demonstration Project. It describes the procedure for enrollment and for termination of enrollment in the Medical Liability Demonstration Project. Further, it sets forth the practice parameters and risk management protocols adopted by the Maine Board of Registration in Medicine, based on the recommendations of the Anesthesiology Medical Specialty Advisory Committee established by 24 M.R.S.A. §2972.

SECTION I: Participation in the Medical Liability Demonstration Project as a specialist in the medical practice of Anesthesiology.

A. Eligibility to Participate: A physician may be enrolled by the Board of Registration in Medicine as a participant in the Medical Liability Demonstration Project if:

1. He/she have been granted a license to practice medicine and surgery in Maine by the Maine Board of Registration in Medicine and the license so granted is in good standing at the time of enrollment and remains registered as qualifying, pursuant to 32 M.R.S.A. §3280 and Chapter 1, Section 13 of the Board's rules, for the active practice of medicine and surgery within Maine. In addition,

   a. The physician is credentialed to practice anesthesiology in one or more hospital(s) located in Maine, and
   b. A mojority of the physician's practice is in anesthesiology and occurs in such Maine hospital(s).

B. Procedure for Enrollment in the Medical Liability Demonstration Project:

1. Not later than September 1, 1991, the Board of Registration in Medicine will mail to every physician whom it believes to be engaged in the practice of Anesthesiology in Maine a copy of this chapter of its rules and an application form for enrollment as a participant in the Medical Liability Demonstration Project.

2. Until December 31, 1996, any physician who believes

himself/herself eligible for enrollment and participation in the Medical Liability Demonstration Project pursuant to this chapter may request from the Board a copy of these rules and an enrollment application form.

3. Between November 1, 1991 and December 31, 1991, the Board of Registration in Medicine and the Board of Osteopathic Examination & Registration will determine if 50% of all physicians qualifying for enrollment and participation under this chapter have applied. If not, all applicants will be promptly notified and the Medical Liability Demonstration Project, with respect to the specialty medical practice of Anesthesiology will not take place. If the two Boards jointly determine that less than 50% of the eligible physicians have applied for enrollment prior to November 1, 1991, all physicians who have properly applied and who have been found eligible will be notified by their respective licensing board of their enrollment in the Medical Liability Demonstration Project commencing January 1, 1992.

4. At any time until the sooner of: (1) a determination that fewer than 50% of eligible physicians have applied for enrollment prior to November 1, 1991, or, (2) the termination of the Medical Liability Demonstration Project on December 31, 1996, any physician licensed by the Board of Registration in Medicine may request and submit enrollment application forms and, if determined by the Board to be eligible for participation, he/she shall be enrolled in the Medical Liability Demonstration Project.

C. Declination to participate; withdrawal from participation:

1. Enrollment to participate in the Medical Liability Demonstration Project is entirely voluntary and is in no way a consideration or condition of licensure to practice medicine and surgery in Maine. Physicians declining to enroll as participants need do nothing if and when informed by the Board of their right to apply for enrollment. The Board shall, however, deem it a courtesy to be informed by letter of a physician's choice not to enroll.

2. Physicians who have applied to be enrolled as participants and/or who have for sometime been participants in the Medical Liability Demonstration Project may, at any time, withdraw from enrollment by letter request for withdrawal from enrollment sent to the Board offices at State House Station #137, Augusta, ME 04333.

SECTION II: Practice Parameters and Risk Management Protocols for the specialty practice of Anesthesiology:

A. Pursuant to 24 M.R.S.A. §2973, the Board of Registration in Medicine jointly with the Board of Osteopathic Examination & Registration finds the practice parameters and risk management protocols included in Appendix 1 of this Chapter to be consistent with appropriate standards of medical care and levels of quality in the practice of Anesthesiology in Maine.

B. The Board of Registration in Medicine and Board of Osteopathic Examination & Registration hereby jointly adopted the practice parameters and risk management protocols for the practice of Anesthesiology.

BASIS STATEMENT: The practice parameters and risk management protocols for the practice of Anesthesiology in Maine are based on recommendations to the Board of Registration in Medicine and the Board of Osteopathic Examination & Registration by the Medical Specialty Advisory Committee on Anesthesiology which was formed pursuant to 24 M.R.S.A. §2972. The Advisory Committee based its recommendations on studies of medical literature, consultation with experts, analysis of medical malpractice liability claims data, recommended standards of national specialty societies in the field of Anesthesiology, and other sources deemed valid by the committee. In adopting these practice parameters and risk management protocols, it is the desire of the Maine Boards of Registration in Medicine and Osteopathic Examination and Registration that physicians engaged in the practice of anesthesiology in Maine will conform their care of patients to these standards whenever medically appropriate and thereby reduce risk to patients and the cost of defense of claims of negligent substandard care. The Medical Liability Demonstration Project in regard to the specialty practice of Anesthesiology will evaluate the economic and risk benefit effect of the adoption of these standards and their acceptance by practitioners of Anesthesiology in Maine between January 1, 1992 and December 31, 1996, as provided by statute.

AUTHORITY TO ADOPT RULES: 32 M.R.S.A. §3269 and 32 M.R.S.A. §2562; to adopt medical specialty practice parameters and risk management protocols: 24 M.R.S.A. §2973.

EFFECTIVE DATE:

AGENCY COMMENTS AND RESPONSES TO COMMENTS ON PROPOSED RULES: Medical Liability Demonstration Project-Anesthesiology Specialty Practice Parameters and Risk Management Protocols.

The two Boards, which are responsible for licensing of physicians for medical practice in Maine, jointly met in Public Hearing on these Proposed Rules on February 14, 1991 at the Augusta Civic

Center, Augusta, Maine. The Chair of the Medical Specialty Advisory Committee on Anesthesiology spoke of the proposed rules with a recommendation for minor editorial changes which the Boards subsequently found did not materially change the intent of the proposed rules as distributed and announced prior to the hearing. No other persons spoke for or against the proposed rules and no written comment was subsequently received from the public during the comment period which extended to February 25, 1991.

The Advisory Committee recommended, the two Boards subsequently found, that a more restrictive definition than originally proposed of practitioners of anesthesiology eligible for participation in the Medical Liability Demonstration Project by subscription to the adopted practice parameters and risk management protocols was necessary to comply with the intent of enabling statute to secure participation of 50% of the practicing physicians in the state who would actually incorporate the practice parameters and protocols into their general practice of anesthesiology. The original definition discussed by the Advisory Committee included licensed dentists qualified to administer anesthesia and physicians, chiefly surgeons, who medically supervise Certified Nurse Anesthetists. It was determined that the statute, PL 90, Chap 931, had no applicability to the services provided by these professionals.

Other changes recommended by the Advisory Committee at the Public Hearing and subsequently adopted by the two Boards dealt with minor editorial changes throughout the text of the Appendix to Chapter 20 to remove ambiguities of technical language and make explicit in the rule that the basis for deviation from a technical specification, test, or procedure called for in the text, when deemed appropriate by the practitioner in the proper exercise of his/her clinical judgement in a particular case, must be documented in the patient's medical record.

DISCLAIMER:

Most of these standards are developed from the America Society of Anesthesiologists (ASA) standards and guidelines. However, they do not represent ASA policy nor have they received any approval from that body. They should be considered unique to the State of Maine.

The Medical Practice Parameters Committee (Anesthesiology) in Maine has agreed on its first set of parameters. These include:

1. Definitions.
2. Anesthesia record.
3. Intraoperative monitoring standards.
4. Postoperative care standards.
5. Preoperative laboratory testing for anesthesia for ASA I patients undergoing non-major surgery.

I. DEFINITIONS:

Practice parameters in anesthesiology are defined as incorporating standards, guidelines and other patient management strategies that result in high quality of patient care but also recognize that there is a finite limit of resources available for health care.

II. PRACTICE PARAMETERS FOR DOCUMENTATION OF ANESTHESIA CARE.

These practice parameters, which may be exceeded, apply to all patients who receive anesthesia or monitored anesthesia care. Under extenuating circumstances these practice parameters may be modified. When this is the case, the circumstances shall be documented in the record.

Documentation is a factor in the provision of quality care. The final responsibility for the record rests with the physician responsible for anesthesia care. Anesthesia is usually viewed as consisting of preanesthesia, perianesthesia, and postanesthesia components. Anesthesia care should be documented to reflect these components and to facilitate review. The anesthetic record should be easily interpreted and use abbreviations that are widely accepted.

The record should include documentation of:

A. Preanesthesia Evaluation

1. Review of medical record

a. Pertinent objective diagnostic data (e.g. lab, EKG, CXR)
b. Old chart review of pervious anesthetics when

available and pertinent.

2. Patient interview

   a. Medications
   b. Allergies
   c. Previous anesthetic experiences
      (1) Family history of anesthesia problems
   d. Pertinent review of systems

3. Physical exam appropriate to anesthesia care

   a. Special notation of airway to dentition.

4. ASA Physical status

5. Formulation and discussion of an anesthesia plan with the patient and/or responsible adult, including consent to that plan.

B. Perianesthesia

1. Immediate review prior to initiation of anesthetic procedure

   a. Record
   b. Patient reevaluation
   c. Check of equipment, drugs, and gas supply

2. Monitoring of the patient

   a. As described in monitoring standards

3. Comment on airway management

4. Amounts of all drugs and agents used, and times given

5. Patient position and protection

6. Management of fluids

   a. IV fluids used including blood products
   b. Estimated blood loss
   c. Urine output when appropriate

7. The technique(s) used

8. Unusual events during the anesthesia period

9. The status of the patient at the conclusion of anesthesia

C. Postanesthesia.

1. Patient evaluation on admission and discharge from the postanesthesia care unit.

2. A time based record of vital signs and level of consciousness.

3. All drugs administered and their dosages.

4. Type and amount of intravenous fluids administered including blood and blood products.

5. Any unusual events including postanesthesia or post-procedural complications.

6. Medical interventions.

III. ANESTHESIA STANDARDS FOR BASIC INTRAOPERATIVE MONITORING.

These standards apply to all anesthesia care (although, in emergency circumstances, appropriate life support measures take precedence). These standards may be exceeded at any time based on the judgement of the responsible anesthesiologist. They are intended to encourage high quality patient care, but observing them may not guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice. This set of standards addresses only the issue of basic intraoperative monitoring, which is one component of anesthesia care. In certain rare or unusual circumstances, (1) some of these methods of monitoring may be clinically impractical, and (2) appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continual(+) monitoring may be unavoidable. Under extenuating circumstances, the responsible anesthesiologist may waive the requirements marked with an asterisk (*) when this is done, it shall be stated (including the reasons) in a note in the patient's anesthetic record. These standards are not intended for application to the care of the obstetrical patient in labor or in the conduct of pain management.

(+)Note that "continual" is defined as "repeated regularly and frequently in steady rapid succession" whereas "continuous" means prolonged without any interruption at any time."

Definition: Anesthesia is defined as all types of anesthesia care, unless otherwise specified.

A. Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.

OBJECTIVE:

Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care. In the event there is a direct known hazard, e.g., radiation, to the anesthesia personnel which might require intermittent remote observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthetic, the best judgement of the anesthesiologist will be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence.

B. During all anesthetics, the patient's oxygenation, ventilation, and circulation shall be continually evaluated.

OXYGENATION

OBJECTIVE:

To ensure adequate oxygen concentration in the inspired gas of the blood.

METHODS:

1. Anesthesia machines capable of delivering less than 18% oxygen shall not be in use.

2. Inspired gas: During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm in use.*

3. Blood oxygenation: A quantitative method of assessing oxygenation such as pulse oximetry shall be employed* Adequate illumination and exposure of the patient is necessary to assess color.*

VENTILATION

OBJECTIVE:

To ensure adequate ventilation of the patient.

METHODS:

1. Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. While qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and ausculation of breath sounds may be adequate,

quantitative monitoring of the CO2 content and/or volume of expired gas is encouraged.

2. When an endotracheal tube is inserted, its correct position in the trachea must be verified by clinical assessment and end-tidal CO2 analysis.*

3. Ongoing evaluation of mechanical ventilation must be assessed by any or all of the following: A.) Clinical assessment, B.) capnometry, C.) mechanical tidal volume and rate measurement.

4. When ventilation is controlled by a mechanical ventilator, there shall be in continuous use a device that is capable of detecting disconnection of components of the breathing system. The device must give an audible signal when its alarm threshold is exceeded.

5. During regional anesthesia and monitored anesthesia care, the adequacy of ventilation shall be evaluated, at least, by continual observation of qualitative clinical signs.

CIRCULATION

OBJECTIVE:

To ensure the adequacy of the patient's circulatory function during all anesthetics.

METHODS:

1. Every patient receiving anesthesia shall have the electrocardiogram continuously displayed from the beginning of anesthesia until preparing to leave the anesthetizing location.*

2. Every patient receiving anesthesia shall have arterial blood pressure and heart rate determined and evaluated at least every five minutes.*

3. Every patient receiving general anesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one of the following: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intraarterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry.

C. DISCRETIONARY PHYSIOLOGIC MONITORS.

BODY TEMPERATURE

OBJECTIVE:

To aid in the maintenance of appropriate body temperature during all anesthetics.

METHODS:

There shall be readily available a means to continuously measure the patient's temperature. When changes in body temperature are intended, anticipated or suspected, the temperature shall be measured.

IV. STANDARDS FOR POSTANESTHESIA CARE.

These standards apply to postanesthesia care in all locations. These standards do not apply to Obstetric Epidural Analgesia or Pain Management. These standards may be exceeded based on the judgement of the responsible anesthesiologist. They are intended to encourage high quality patient care, but cannot guarantee any specific patient outcome. Extenuating circumstances may require deviation from the standard, but a note in the patient's record concerning any deviation, will be made in a timely fashion. They are subject to revision from time to time as warranted by the evolution of technology and practice.

A. All patients who have received general anesthesia, regional anesthesia, or monitored anesthesia care shall receive appropriate postanesthesia management.

   1. A Postanesthesia Care Unit (PACU) or an area which provides equivalent postanesthesia care shall be available to receive patients after surgery and anesthesia. All patients who receive anesthesia shall be admitted to the PACU except by specific order of the anesthesiologists responsible for the patient's care.

   2. The medical aspects of care in the PACU shall be governed by policies and procedures which have been reviewed and approved by the Department of Anesthesiology.

   3. The design, equipment and staffing of the PACU shall meet requirements of the facility's accrediting and licensing bodies.

   4. The nursing standards of practice shall be consistent with those approved in 1986 by the American Society of Post Anesthesia Nurses (ASPAN).

B. A patient transported to the PACU shall be accompanied by a member of the Anesthesia Care Team who is knowledgeable about the patient's condition. The patient shall be continually evaluated and treated during transport with

monitoring and support appropriate to the patient's condition.

C. Upon arrival in the PACU, the patient shall be reevaluated and a verbal report provided to the responsible PACU nurse by the member of the Anesthesia Care Team who accompanies the patient.

1. The patient's status on arrival in the PACU shall be documented.

2. Information concerning the preoperative condition and the surgical/anesthetic course shall be transmitted to the PACU nurse.

3. The member of the Anesthesia Care Team shall remain in the PACU until the PACU nurse accepts responsibility for the nursing care of the patient.

D. The patient's condition shall be evaluated continually in the PACU.

1. The patient shall be observed and monitored by methods appropriate to the patient's medical condition. Particular attention should be given to monitoring oxygenation, ventilation and circulation. During recovery a quantitative method of assessing oxygenation such as pulse oximetry shall be employed.

2. An accurate written report of the PACU period shall be maintained.

3. General medical supervision and coordination of patient care in the PACU should be the responsibility of an anesthesiologist.

4. There shall be a physician in the facility capable of managing complications and providing cardiopulmonary resuscitation for patients in the PACU.

E. A physician is responsible for the discharge of the patient from the Postanesthesia Care Unit.

1. When discharge criteria are used, they must be approved by the Department of Anesthesiology. They may vary depending upon whether the patient is discharged to a hospital room, to the ICU, to a short stay unit, or home.

2. In the absence of the physician responsible for the discharge, the PACU nurse shall determine that the patient meets the discharge criteria. The name of the physician accepting responsibility for discharge shall be noted in the record.

V. PREOPERATIVE LABORATORY TESTING.

A. ANESTHESIA PREOPERATIVE TESTING

ASA Physical Status. I. (Healthy with no underlying acute or chronic diseases).

Pathology. None. (only variables are age and sex).

Procedure. Excludes extensive major body cavity, expected significant (10%) blood loss or extensive manipulation of physiological variables.

Age/Sex	General.Sp/Epi.**	MAC**	P. Blk.**	IV Blk.**	Local.
0-6 mos.					
Both.	Hct.	0	0	0	0
Time span.	1 mos.				
6 mos. - 14 yrs					
Both	0	0	0	0	0
14 - Menopause					
Female	Hct.	0	0	0	0
Time span	6 mos.				
15 - 50					
Male	0	0	0	0	0
Menopause - 50 yrs.					
Female	0	0	0	0	0
50 - 60 yrs.					
Both	Hct. 6 mos. EKG 1 yr. BUN/Gluc 6 mos.	Hct. 6 mos. EKG 1 yr. BUN/Gluc 6 mos.	Hct. 6 mos.	0	0	0
Over 60 yrs.					
Both	---- As Above Plus ----				
	CXR 1 yr.	CXR 1 yr.	EKG 1 yr. BUN/Gluc. 6 mos.	6 mos.	0	0

Procedures with potential for significant blood loss.

MinimumHct.

2 weeks

Optional T & S etc.

**Sp/Epi = Spinal/Epidural, MAC = Monitored Anesthesia Care, P. Block - Peripheral Block (i.e. Axillary etc), I.V. Block = Bier.

B. ANESTHETIC PREOPERATIVE TESTING CRITERIA

Criteria.

1. Each patient will have an appropriate preoperative history and physical examination prior to the proposed surgery.

2. These preoperative parameters only apply to the anesthetic management of the patient. The surgical management of the patient may require additional testing though frequently there will be overlap.

3. These parameters only apply to elective surgery.

4. These parameters do NOT apply to those patients who are going to have:

   a. Surgery involving extensive major body cavity procedures.
   b. Surgery with anticipated major blood loss.
   c. Surgery requiring extensive manipulation of physiological variables.

5. These parameters do NOT apply to those patients who have developed an acute process in addition to or separate from the surgical process necessitating the operation.

6. Duplicate data is acceptable provided it meets the following criteria:

   a. The name of the physician (clinic/office) managing the patient's disease.
   b. The location of the practice if not in the immediate vicinity.
   c. At least a verbal report, which may come from the patient if the patient is felt to be a reliable historian, of any indicated tests. Hard copy is preferred.
   d. The approximate date of the test.

7. The anesthetic preoperative evaluation and testing is directed towards developing the appropriate anesthetic care plan. It is not the equivalent of or a substitute for an annual physical examination or other similar screening process.

C. ANESTHETIC PREOPERATIVE TESTING

American Society of Anesthesiologists (ASA) Status.

The ASA has a patient acuity classification I - VI. This reflects the medical status of the patient prior to the surgery. As such it represents a combination of both acute and chronic diseases. It does NOT reflect the magnitude of the proposed surgery. It is not age dependent.

ASA I Health patient.

ASA II. Mild systemic disease. No functional limitation.

ASA III. VI will be described later as required.

02-373 BOARD OF REGISTRATION IN MEDICINE

Chapter 22: Medical Liability Demonstration Project - Emergency Medicine Specialty Practice Parameters and Risk Management Protocols.

SUMMARY: This chapter implements 24 M.R.S.A. c. 21, sub-c IX by defining the eligibility requirements for enrollment of Maine licensed allopathic physicians practicing in the medical specialty of Emergency Medicine in the Medical Liability Demonstration Project. It describes the procedure for enrollment and for termination of enrollment in the Medical Liability Demonstration Project. Further, it sets forth the practice parameters and risk management protocols adopted by the Maine Board of Registration in Medicine, based on the recommendations of the Emergency Medicine Medical Specialty Advisory Committee established by 24 M.R.S.A. §2972.

SECTION I: Participation in the Medical Liability Demonstration Project as a specialist in the medical practice of Emergency Medicine.

A. Eligibility to Participate: A physician may be enrolled by the Board of Registration in Medicine as a participant in the Medical Liability Demonstration Project if:

1. He/she have been granted a license to practice medicine and surgery in Maine by the Maine Board of Registration in Medicine and the license so granted is in good standing at the time of enrollment and remains registered as qualifying, pursuant to 32 M.R.S.A. §3280 and Chapter 1, Section 13 of the Board's rules, for the active practice of medicine and surgery within Maine. In addition,

   a. The physician is credentialed to practice Emergency Medicine in one or more hospital(s) located in Maine, and
   b. A majority of the physician's practice is in clinical Emergency Medicine and occurs in such Maine hospital(s).

2. The physician makes application to the Board on a form provided by the Board and is thereafter approved for participation by the Board based on satisfactory evidence.

B. Procedure for Enrollment in the Medical Liability Demonstration Project:

1. Not later than September 1, 1991, the Board of Registration in Medicine will mail to every physician whom it believes to be engaged in the practice of Emergency Medicine in Maine a copy of this chapter of

its rules and an application form for enrollment as a participant in the Medical Liability Demonstration Project.

2. Until December 31, 1996, any physician who believes himself/herself eligible for enrollment and participation in the Medical Liability Demonstration Project pursuant to this chapter may request from the Board a copy of these rules and an enrollment application form.

3. Between November 1, 1991 and December 31, 1991, the Board of Registration in Medicine and the Board of Osteopathic Examination & Registration will determine if 50% of all physicians qualifying for enrollment and participation under this chapter have applied. If not, all applicants will be promptly notified and the Medical Liability Demonstration Project, with respect to the specialty medical practice of Emergency Medicine will not take place. If the two Boards jointly determine that less than 50% of the eligible physicians have applied for enrollment prior to November 1, 1991, all physicians who have properly applied and who have been found eligible will be notified by their respective licensing board of their enrollment in the Medical Liability Demonstration Project commencing January 1, 1992.

4. At any time until the sooner of: (1) a determination that fewer than 50% of eligible physicians have applied for enrollment prior to November 1, 1991, or, (2) the termination of the Medical Liability Demonstration Project on December 31, 1996, any physician licensed by the Board of Registration in Medicine may request and submit enrollment application forms and, if determined by the Board to be eligible for participation, he/she shall be enrolled in the Medical Liability Demonstration Project.

C. Declination to participate; withdrawal from participation:

1. Enrollment to participate in the Medical Liability Demonstration Project is entirely voluntary and is in no way a consideration or condition of licensure to practice medicine and surgery in Maine. Physicians declining to enroll as participants need do nothing if and when informed by the Board of their right to apply for enrollment. The Board shall, however, deem it a courtesy to be informed by letter of a physician's choice not to enroll.

2. Physicians who have applied to be enrolled as participants and/or who have for sometime been participants in the Medical Liability Demonstration

Project may, at any time, withdraw from enrollment by letter request for withdrawal from enrollment sent to the Board offices at State House Station #137, Augusta, ME 04333.

SECTION II: Practice Parameters and Risk Management Protocols for the specialty practice of Emergency Medicine:

A. Pursuant to 24 M.R.S.A. §3280, the Board of Registration in Medicine jointly with the Board of Osteopathic Examination & Registration finds the practice parameters and risk management protocols included in Appendix 1 of this Chapter to be consistent with appropriate standards of medical care and levels of quality in the practice of Emergency Medicine in Maine.

B. The Board of Registration in Medicine and Board of Osteopathic Examination & Registration hereby jointly adopted the practice parameters and risk management protocols for the practice of Emergency Medicine.

BASIS STATEMENT: The practice parameters and risk management protocols for the practice of Emergency Medicine in Maine are based on recommendations to the Board of Registration in Medicine and the Board of Osteopathic Examination & Registration by the Medical Specialty Advisory Committee on Emergency Medicine which was formed pursuant to 24 M.R.S.A. §2972. The Advisory Committee based its recommendations on studies of medical literature, consultation with experts, analysis of medical malpractice liability claims data, recommended standards of national specialty societies in the field of Emergency Medicine, and other sources deemed valid by the committee. In adopting these practice parameters and risk management protocols, it is the desire of the Maine Boards of Registration in Medicine and Osteopathic Examination and Registration that physicians engaged in the practice of Emergency Medicine in Maine will conform their care of patients to these standards whenever medically appropriate and thereby reduce risk to patients and the cost of defense of claims of negligent substandard care. The Medical Liability Demonstration Project in regard to the specialty practice of Emergency Medicine will evaluate the economic and risk benefit effect of the adoption of these standards and their acceptance by practitioners of Emergency Medicine in Maine between January 1, 1992 and December 31, 1996, as provided by statute.

AUTHORITY TO ADOPT RULES: 32 M.R.S.A. §3269 and 32 M.R.S.A. §2562; to adopt medical specialty practice parameters and risk management protocols: 24 M.R.S.A. §2973.

EFFECTIVE DATE:

AGENCY COMMENTS AND RESPONSES TO COMMENTS ON PROPOSED RULES: Medical Liability Demonstration Project-Emergency Medicine Specialty Practice Parameters and Risk Management Protocols.

The two Boards, which are responsible for licensing of physicians for medical practice in Maine, jointly met in Public Hearing on these Proposed Rules on February 14, 1991, at the Augusta Civic Center, Augusta, Maine. There were no speakers for or against Chapter 22 of the proposed rules relating to practice parameters and risk management protocols for use in the specialty practice of Emergency Medicine.

No consumers submitted written comment on the proposed rules. Five physicians licensed for medical practice in the state submitted written comment during the period allowed. Generally, these commented on the definition of those eligible to subscribe to the proposed practice parameters and risk management protocols, and thereby participate in the Medical Liability Demonstration Project, as set forth in proposed Chapter 22, Section 1. The writers pointed out that they, as many other physicians, provide care to patients in the setting of a hospital emergency department. Others accept responsibility pursuant to existing Board rules, for Physician Assistants and Certified Nurse Practitioners employed by hospitals in emergency departments. Several writers pointed out a confusing aspect of the format of the proposed standard for Cervical Spine x-ray studies in that the procedure for discharge instructions seemed to be set forth as a separate protocol rather than, as intended, to be a continuation of the Cervical Spine x-ray protocol. One writer expressed concern that the proposed protocols were limited to clinical situations, potential cervical spine injury and transfer between institutions. He recommended additional topics for consideration in the future.

After consideration of these written comments and after discussion with the Cochairs of the Medical Specialty Advisory Committee on Emergency Medicine, the two Boards subsequently found that the definition originally proposed of practitioners of Emergency Medicine eligible for participation in the Medical Demonstration Project by subscription to the adopted practice parameters and risk management protocols did not entirely conform with the intent of the enabling statute to secure participation of 50% of the practicing physicians in the state who would actually wish to incorporate the practice parameters and protocols into their general practice of emergency medicine. The Boards found that a clarification of Chapter 22, Section 1 defining those eligible to participate in the Demonstration Project was in order and that such change would not materially change the meaning or effect of the rule as proposed for public comment or as intended in the enabling legislation. As finally adopted, the rule will limit eligibility to participate to those physicians credentialed and privileged to practice Emergency Medicine in one or more Maine hospitals and a majority of whose medical practice is in clinical Emergency Medicine occurs in one

of those Maine hospitals. Thus, eligibility to participate in the Medical Liability Demonstration Project for the Specialty of Emergency Medicine will be limited to those specialist practicing Emergency Medicine at least 50% of their clinical time. The Boards find that this is a proper interpretation of the statutory intent.

In regard to additional protocols for other clinical situations, the Boards acknowledge that the Specialty Advisory Committee on Emergency Medicine is continuing its work to develop other practice parameters and risk management protocols for other clinical presentations which may subsequently be proposed for incorporation in rules as the Medical Liability Demonstration Project goes forward. The suggestions of the writer have been referred to the Advisory Committee for evaluation and study.

Other changes recommended by authors of written comment were adopted by the two Boards to deal with minor editorial changes at points in the text of the Appendix to Chapter 22 to remove ambiguities of technical language. The Boards found these minor editorial changes were clarifying and expansive rather than substantive changes to the meaning of the text and originally proposed.

PREAMBLE

Pursuant to Public Law Chapter 931, the Medical Specialty Advisory Committee on Emergency Medicine has developed the following Practice Parameters/Risk Management Protocols for use by participating emergency practitioners in the state of Maine.

In so doing, we have accepted the definition of Practice Parameters adopted by the American Medical Society:

> Practice parameters are strategies of patient management, developed to assist physicians in clinical decision-making. Practice parameters include standards, guidelines, and other patient management strategies. Standards are accepted principles for patient management. Guidelines are recommendations for patient management which identify a particular management strategy or a range of management strategies. Other strategies for patient management include practice policies and practice options.

It is the opinion of the committee that these Practice Parameters, so defined and developed, comply with the requirements for both Practice Parameters and Risk Management Protocols as required in the law.

I. CERVICAL SPINE X-RAYS ACUTE TRAUMA PATIENTS

Recent studies, and critical review of earlier literature, reveal that truly asymptomatic C-spine injuries do not occur in alert patients without other significant painful injuries. Therefore, routine C-spine x-rays and immobilization are not indicated for these patients.

A. Criteria for not Obtaining Cervical Spine Films.

Significant cervical spine injury is assumed not to be present and C-spine films are not mandatory for trauma patients who most the following criteria:

1. No complaint of cervical spine pain.

2. No localized cervical spine tenderness by palpation.

3. No subjective or objective findings of spinal cord or nerve root injury.

   a. Subjective: Weakness or paresthesia
   b. Objective: Motor or sensory deficit

4. Have a reliable history and physical exam and appropriate response. (appropriate response from patient)

B. Obtaining C-Spine X-Rays

1. When c-spine x-rays are deemed necessary, adequate lateral films, which demonstrate all seven cervical vertebrae, should be obtained with the patient's neck immobilized. A swimmer's view may be required to see all seven cervical vertebrae.

2. After clearing the lateral view, AP and odontoid views may be obtained. Immobilization should be continued if clinically indicated.

3. If plain films are unsatisfactory, or are negative but the clinical suspicion of a c-spine injury remains, additional films and/or CT scan may be indicated.

C. Discharge Instructions

When the emergency practitioner determines that a patient may be discharged, the following written instructions should be documented on the Emergency Department medical record and signed by the patient:

1. Specific advice regarding recommended treatment and/or medications relating to the patient's clinical problem;

2. Information about follow-up, if needed, which includes the name of an appropriate physician and/or clinic and a suggested time period in which the patient should be seen;

3. Instructions to call or return to the Emergency Department if symptoms progress or if the patient encounters difficulty in implementing the suggested follow-up plans.

II. CHECK LIST FOR TRANSFER OF PATIENTS TO OTHER HOSPITALS

SENDING HOSPITAL:_____

NAME:_____ DATE:_____

RECEIVING HOSPITAL:_____

RECEIVING PHYSICIAN:_____

RECEIVING HOSPITAL ADMIN REPRESENTATIVE: _____

Y	No	1.	Patient stabilized. (if unstable reason documented on chart.)
Y	NA	2.	Reasons for and the risks/benefits of transfer explained to the patient/family and documented on chart.
Y	No	3.	Patient/guardian signed Transfer Consent forms.
Y	NA		a. Patient unable to sign.
Y	NA		b. No guardian present.
Y	NA	4.	Contact made with the accepting physician, case reviewed, the physician accepts the patient.
Y	NA	5.	Receiving institution administrative representative accepts patient.
Y	NA	6.	Notified the receiving nurse of the patient's condition and transport arrangements.
Y	NA	7.	Arranged appropriate transportation.
Y	NA	8.	The necessary trained personnel will accompany the patient with appropriate equipment, including:
Y	NA		a. medical personnel qualified to handle the existing condition and anticipated problems.
Y	NA		b. appropriate IV access.
Y	NA		c. appropriate airway management.
Y	NA		d. appropriate medications.
Y	NA		e. orders regarding monitoring Vital Signs and Medical Control.
Y	NA	9.	The patient's stability was reassessed immediately prior to transfer. Unstable patients should only be transferred when the hospital lacks the capability to stabilize the patient.
Y	NA	10.	All appropriate, if available, medical records, including the completed Emergency Department chart, X-ray, Lab, and EKG reports are to accompany the patient or be faxed to the facility.
Y	NA	11.	Care of the patient should be formally accepted by appropriate medical personnel at the receiving facility.

*Whenever No/NA circled, document why.

PHYSICIAN'S SIGNATURE:_____

TABLE 1 COBRA DEFINITIONS

An emergency medical condition means a condition which manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in

(i) placing the health of the individual (or with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, or

(ii) serious impairment to bodily functions, or

(iii) serious dysfunction of any bodily organ or part.

A patient is in active labor if she is having contractions, and

(i) there is inadequate time to effect a safe transfer to another hospital before delivery, or

(ii) the transfer may pose a threat to the health or safety of the woman or the unborn child.

A patient's condition has been stabilized if no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility. A patient in active labor has been stabilized if she has delivered (including the placenta).

02-373 BOARD OF REGISTRATION IN MEDICINE

Chapter 24: Medical Liability Demonstration Project - Obstetrics and Gynecology Specialty Practice Parameters and Risk Management Protocols.

SUMMARY: This chapter implements 24 M.R.S.A. c. 21, sub-c IX by defining the eligibility requirements for enrollment of Maine licensed allopathic physicians practicing in the medical specialty of Obstetrics and Gynecology in the Medical Liability Demonstration Project. It describes the procedure for enrollment and for termination of enrollment in the Medical Liability Demonstration Project. Further, it sets forth the practice parameters and risk management protocols adopted by the Maine Board of Registration in Medicine, based on the recommendations of the Obstetrics and Gynecology Medical Specialty Advisory Committee established by 24 M.R.S.A. §2972.

SECTION I: Participation in the Medical Liability Demonstration Project as a specialist in the medical practice of Obstetrics and Gynecology.

A. Eligibility to Participate: A physician may be enrolled by the Board of Registration in Medicine as a participant in the Medical Liability Demonstration Project if:

1. He/she have been granted a license to practice medicine and surgery in Maine by the Maine Board of Registration in Medicine and the license so granted is in good standing at the time of enrollment and remains registered as qualifying, pursuant to 32 M.R.S.A. §3280 and Chapter 1, Section 13 of the Board's rules, for the active practice of medicine and surgery within Maine. In addition,

2. The physician makes application to the Board on a form provided by the Board and is thereafter approved for participation by the Board based on satisfactory evidence that he/she engages regularly in the provision of, or medical supervision of others engaged in the provision of, prenatal care to women, obstetrical delivery or termination of pregnancy, and postpartum care. Such evidence may include, but is not limited to one or more of the following criteria:

   a. The physician, regardless of primary medical practice specialty, holds medical staff privileges to perform obstetrical and gynecological procedures granted by a Maine licensed hospital pursuant to the Medical Staff Bylaws of that institution.

b. The physician holds himself out to the public and to his professional colleagues as having expertise in the diagnosis and treatment of gynecological conditions and obstetrical care of pregnant women and is generally recognized as professionally competent to do so.

c. The physician is eligible for or certified by the American Board of Obstetrics and Gynecology.

d. The physician is a member in good standing of the American College of Obstetrics and Gynecology and/or its Maine chapter.

B. Procedure for Enrollment in the Medical Liability Demonstration Project:

1. Not later than September 1, 1991, the Board of Registration in Medicine will mail to every physician whom it believes to be engaged in the practice of Obstetrics and Gynecology in Maine a copy of this chapter of its rules and an application form for enrollment as a participant in the Medical Liability Demonstration Project.

2. Until December 31, 1996, any physician who believes himself/herself eligible for enrollment and participation in the Medical Liability Demonstration Project pursuant to this chapter, may request from the Board a copy of these rules and an enrollment application form.

3. Between November 1, 1991 and December 31, 1991, the Board of Registration in Medicine and the Board of Osteopathic Examination & Registration will determine if 50% of all physicians qualifying for enrollment and participation under this chapter have applied. If not, all applicants will be promptly notified and the Medical Liability Demonstration Project, with respect to the specialty medical practice of Obstetrics and Gynecology, will not take place. If the two Boards jointly determine that less than 50% of the eligible physicians have applied for enrollment prior to November 1, 1991, all physicians who have properly applied and who have been found eligible will be notified by their respective licensing board of their enrollment in the Medical Liability Demonstration Project commencing January 1, 1992.

4. At any time until the sooner of: (1) a determination that fewer than 50% of eligible physicians have applied for enrollment prior to November 1, 1991, or, (2) the termination of the Medical Liability Demonstration Project on

December 31, 1996, any physician licensed by the Board of Registration in Medicine may request and submit enrollment application forms and, if determined by the Board to be eligible for participation, he/she shall be enrolled in the Medical Liability Demonstration Project.

C. Declination to participate; withdrawal from participation:

1. Enrollment to participate in the Medical Liability Demonstration Project is entirely voluntary and is in no way a consideration or condition of licensure to practice medicine and surgery in Maine. Physicians declining to enroll as participants need do nothing if and when informed by the Board of their right to apply for enrollment. The Board shall, however, deem it a courtesy to be informed by letter of a physician's choice not to enroll.

2. Physicians who have applied to be enrolled as participants and/or who have for sometime been participants in the Medical Liability Demonstration Project may, at any time, withdraw from enrollment by letter request for withdrawal from enrollment sent to the Board offices at State House Station #137, Augusta, ME 04333.

SECTION II: Practice Parameters and Risk Management Protocols for the specialty practice of Obstetrics and Gynecology:

A. Pursuant to 24 M.R.S.A. §2973, the Board of Registration in Medicine jointly with the Board of Osteopathic Examination & Registration finds the practice parameters and risk management protocols included in Appendix 1 of this Chapter to be consistent with appropriate standards of medical care and levels of quality in the practice of Obstetrics and Gynecology in Maine.

B. The Board of Registration in Medicine and Board of Osteopathic Examination & Registration hereby jointly adopted the practice parameters and risk management protocols for the practice of Obstetrics and Gynecology.

BASIS STATEMENT: The practice parameters and risk management protocols for the practice of Obstetrics and Gynecology in Maine are based on recommendations to the Board of Registration in Medicine and the Board of Osteopathic Examination & Registration by the Medical Specialty Advisory Committee on Obstetrics and Gynecology which was formed pursuant to 24 M.R.S.A. §2972. The Advisory Committee based its recommendations on studies of medical literature, consultation with experts, analysis of medical malpractice liability claims data, recommended standards of national specialty societies in the field of Obstetrics and Gynecology, and other sources deemed valid by the committee. In

adopting these practice parameters and risk management protocols, it is the desire of the Maine Boards of Registration in Medicine and Osteopathic Examination and Registration that physicians engaged in the practice of Obstetrics and Gynecology in Maine will conform their care of patients to these standards whenever medically appropriate and thereby reduce risk to patients and the cost of defense of claims of negligent substandard care. The Medical Liability Demonstration Project in regard to the specialty practice of Obstetrics and Gynecology will evaluate the economic and risk benefit effect of the adoption of these standards and their acceptance by practitioners of Obstetrics and Gynecology in Maine between January 1, 1992 and December 31, 1996, as provided by statute.

AUTHORITY TO ADOPT RULES: 32 M.R.S.A. §3269 and 32 M.R.S.A. §2562; to adopt medical specialty practice parameters and risk management protocols: 24 M.R.S.A. §2973.

EFFECTIVE DATE:

AGENCY COMMENTS AND RESPONSES TO COMMENTS ON PROPOSED RULES: Medical Liability Demonstration Project-Obstetrics and Gynecology Specialty Practice Parameters and Risk Management Protocols.

The two Boards, which were responsible for licensing of physicians for medical practice in Maine, jointly met in Public Hearing on these proposed rules on February 14, 1991, at the Augusta Civic Center, Augusta, Maine. The Chair of the Medical Specialty Advisory Committee on Obstetrics and Gynecology spoke in favor of Chapter 24 of the proposed rules relating to practice parameters and risk management protocols for use in the specialty practice of Obstetrics and Gynecology. There were no other speakers for or against the proposal.

No consumers submitted written comment on the proposed rules. Seven physicians licensed for medical practice in the state submitted written comment during the period allowed. One commented on the definition of those eligible to subscribe to the proposed practice parameters and risk management protocols, and thereby participate in the Medical Liability Demonstration Project, as set forth in proposed Chapter 24, Section 1. The writer questioned if Family Practice physicians who engage in obstetrical care of women were included. The Boards found that the existing definition made clear that they were, as were surgeons who engage in gynecological procedures but not obstetrics. Several writers pointed out ambiguities in technical language in the Appendix at several points or legitimate differences in professional opinion as to the efficacy of one test or clinical sign over another. In general, the two Boards found these comments to be valid and minor changes in the text have been adopted to make the language more clear and, where appropriate without diminishing the standard, more permissive in regard to recognition of the efficacy of varying clinical signs, diagnostic test and measures.

After consideration of these written comments and after discussion with the Chairs of the Medical Specialty Advisory Committee on Obstetrics and Gynecology, the Boards found that the adoption of these changes to prop' 'd Chapter 24 and its Appendix was in order and that such changes .o not materially change the meaning or effect of the rule as proposed for public comment or as intended in the enabling legislation. The Boards are appreciative of the views of the writers and the effort made by the authors to communicate and share clinical expertise and professional opinion with the Boards.

MEDICAL LIABILITY DEMONSTRATION PROJECT
OBSTETRICS AND GYNECOLOGY PRACTICE PARAMETERS

CONTENTS:

I. PROCEDURE: Cesarean Delivery for Failure to Progress (74 allz; subcode dependent on which type of procedure is used)

A. Indication: Lack of progress (failure to progress) (600.61-failed trial of labor; 662.11-long labor)

Confirmation of Indication:

1. No change in either dilation of cervix or descent of presenting part after at least 2 hours of active labor.

2. Active labor indicated by:

a. Cervix dilated to at least 3 cm in nullipara or 4 cm in multipara;
b. Contractions at least every 2-3 minutes;
c. Strength of contractions at least 50 mm Hg internal pressure as measured by intrauterine catheter or inability to indent fundus on palpation at height of contraction.

B. Actions prior to Procedure:

1. Rupture membranes.

2. In absence of active labor, administer oxytocin to augment labor.

3. Hydrate patient.

4. Obtain anesthesia consultation and evaluation.

5. Ensure that qualified personnel* are in attendance for resuscitation and care of newborn.

6. Informed consent.

7. Fetal Heart Rate prior to surgery.

8. Vaginal examination prior to surgery.

Reference: Quality Assurance in Obstetrics & Gynecology-1989 Ed.

*To be determined in writing by each institution

II. PROCEDURE: Assessment of Fetal Maturity prior to repeat Cesarean delivery or elective induction of labor.

A. Indication: To prevent fetal pulmonary immaturity and

to determine the appropriate time of elective C-section or elective induction of labor.

Confirmation of Indication: One of the following

1. Clinical Criteria needed to confirm a term gestation are:

   a. Fetal heart tones have been demonstrated for at least 18 completed weeks by nonelectronic fetoscope or at least 25 completed weeks by Doppler ultrasound; and
   b. Appropriate uterine size was established by pelvic examination prior to 16 weeks of gestation.

2. Ultrasound determinations needed to confirm a term gestation:

   a. Gestational age based on the measurement of crown-rump length obtained between 6-12 weeks of gestation, or
   b. Other ultrasound confirmation of gestational age was obtained before 24 weeks of gestation.

3. If these criteria are not met, amniotic fluid analysis by a recognized test may provide satisfactory evidence of fetal lung maturity; OR

4. The onset of spontaneous labor.

References: ACOG tech. bulletin #110, ACOG Committee Opinion #77 and Harvard Medical Institutional Clinical Standard #11.

III. PROCEDURE: Hysterectomy, abdominal (68.4) or vaginal (68.5)

A. Indication: Leiomyomata (218.0-218.9)

Confirmation of Indication:

Present of 1 or more of the following:

1. Asymptomatic myomata associated with a uterine size equal to or larger than that after 12 weeks gestation*, determined by physical examination or ultrasound examination.

2. Excessive uterine bleeding evidenced by either a or b:

   a. Bleeding for more than 8 days during more than

a single cycle and profuse bleeding ** requiring additional protection;

b. Anemia due to acute or chronic blood loss.

3. Chronic pelvic pain for > 6 months with a negative effect on patient's quality of life.

4. Rapid growth in size of uterus/myomata, to a point equal to or larger than that after 12 weeks gestation.

B. Actions Prior to Procedure:

1. Confirm by cytologic study the absence of cervical pathology. No malignancy.

2. Obtain endometrial sample or perform D&C (when abnormal bleeding is present).

3. Document and attempt to correct anemia if present.

4. Offer autologous blood donation if appropriate.

5. Document patient education and informed consent.

C. Contraindication:

1. Desire to maintain fertility.

References: Quality Assurance if Obstetrics & Gynecology-1989 Ed.

*Transverse measurement of at least 8 cm or weight of 280 g or more (see Table 1). (included)

**For example, large clots, gushes, limitations on activity.

Unless otherwise stated, each numbered and lettered item (except contraindication) must be present.

TABLE 1

UTERINE SIZE AND WEIGHT

Type of Uterus	Size (cm)	Weight (g)
Normal Uterus		
Nulliparous	5	70
Multiparous	6	75-125
Enlarged Uterus (gestational age)		
8 weeks	6	125-150
12 weeks	8	280-320
24 weeks	18	580-620
Term		1,000-1,100

IV. PROCEDURE: Hysterectomy, abdominal (68.4) or vaginal (68.5)

A. Indication: Abnormal uterine bleeding in women of reproductive age (626 all, except 626.0, 626.1, 626.3, 626.7)*

Confirmation of Indication:

1. History of all of the following:

   a. Excessive uterine bleeding or irregular uterine bleeding defined as bleeding for more than 8 days during more than a single cycle and profuse bleeding requiring additional protection**;
   b. No history of a bleeding diathesis or use of medication that may cause bleeding;
   c. Negative effect on patient's quality of life.

2. Failure to find on physical examination, uterine or cervical pathology that would cause abnormal bleeding.

3. Laboratory data

   a. No finding of endometrial neoplasia;
   b. No malignancy found in cytological studies of cervix;

4. No finding of endometrial polyps by D&C, hysterscopy, or, hysterogram.

B. Actions Prior to Procedure:

1. Determine that attempted hormone treatment (estrogen-progestogen) was not successful or contraindicated or refused.

2. Hemoglobin or hematocrit documented.

3. Document and attempt to correct anemia if present.

4. Offer autologous blood donation if appropriate.

5. Document patient education and informed consent.

C. Contraindication:

1. Desire to maintain fertility.

Reference: Quality Assurance in Obstetrics & Gynecology-1989 Ed.

*Other diagnosis that should also be evaluated according to these criteria include menorrhagia (626.2, 627.0), hypermenorrhea (626.2)

**For example, large clots, gushes, limitations on activity.

V. TREATMENT: Tocolysis

A. Indication: Preterm Labor

Confirmation of Indication: 1 and 2, and either 3 or 4

1. Gestational age between 20 and 37 weeks confirmed by dates or ultrasound.

2. Frequent, regular uterine contractions preferably documented by a tocodynomometer.

3. Documented progressive change in the cervix.

4. Cervical dilation >2 cm and effacement >80%.

B. Actions Prior to Treatment:

1. Between 34 and 37 weeks gestation an individual treatment plan is required.

2. For patient less than 34 weeks:

   a. Document historical risk factors which may include:
      (1) Previous preterm labor or delivery;
      (2) Pyelonephritis;
      (3) Heavy smoking;
      (4) Hypertension;
      (5) Uterine anomaly;
      (6) Age <16 or > 40 years;
      (7) Overdistension of the uterus;
   b. Bed rest;
   c. Adequate hydration;
   d. Documented fetal heart rate and uterine activity monitoring;
   e. Ultrasound to confirm date and rule out anomalies;
   f. Pelvic examine to confirm cervical status;
   g. Laboratory studies including:
      (1) CBC;
      (2) Urine for culture and sensitivity; and
      (3) Group B beta hemolytic strep culture or rapid identification test;
   h. Consider amniocentesis in afebrile patient.

C. Management:

1. Use of specific drugs should be by individual preference and/or by institutional policies and protocols.

2. Tocolysis should be instituted if contractions persist for >1 hour or there is documented cervical change.

3. Appropriate monitoring during tocolysis may include:

   a. Pulmonary status;
   b. Cardiovascular status;
   c. Glucose;
   d. Clotting factors;

4. Discharge instructions should include:

   a. Instructions regarding early signs of labor;
   b. Early follow-up appointment.

D. Contraindications:

Absolute	Relative
1. Severe hypertension	1. Advanced Labor
2. Fetal compromise	2. Cardiac disease
3. Chorioamnionitis	3. Mild hypertension
4. Severe abruption	4. Hyperthyroidism
5. Severe IUGR	5. Diabetes mellitus
6. Lethal fetal anomaly	6. Mild abruption
7. Severe uterine bleeding	7. Mild IUGR
	8. Fetal anomaly
	9. Stable placenta previa

References: Precis IV; An Update in Obstetrics and Gynecology; Quality Assurance in Obstetrics and Gynecology; The American College of Obstetricians and Gynecologists UNICORN; Guidelines for Obstetrical Care, University of Connecticut Regional Network.

VI. CONDITION: Presumed Ectopic Pregnancy in a clinically stable patient

A. Confirmation of Diagnosis:

1. Documented history consistent with the diagnosis of ectopic pregnancy including any of the following:

   a. Pelvic pain;
   b. Abnormal uterine bleeding;
   c. Risk factors such as previous ectopic, PID, tubal surgery, or IUD usage;
   d. Characteristic menstrual history.

2. Documented physical findings consistent with the diagnosis ectopic pregnancy including any of the following:

   a. Pelvic tenderness;

b. Pelvic mass;
c. Uterine characteristics consistent with pregnancy.

3. Documented laboratory findings consistent with the diagnosis of ectopic pregnancy including any of the following:

a. Positive pregnancy test;
b. Ultrasound findings consistent with pregnancy test results.

B. Management of a Clinically Stable Patient:

1. Ultrasound

a. Assume an intrauterine pregnancy if a fetal sack is visualized in the uterine cavity;
b. If no fetal sack is visualized then:
(1) Obtain a baseline quantitative serum bHCG;
(2) Advise patient of warning signs of ectopic pregnancy;
(3) Repeat bHCG every 48-72 hours looking for doubling;

(a) If value doubles every 48 hours, repeat ultrasound until an IUP is confirmed;
(b) If doubling does not occur, ectopic or nonviable IUP should be suspected and management depends on the clinical and laboratory evaluations;

1. Consult and/or referral to a specialist should be considered;
2. Recommend serial studies until diagnosis is confirmed;
3. Falling bHCG levels can be successfully followed without surgical intervention, provided the patient remains hemodynamically stable and has no other findings that prompt surgical intervention;
4. Consider hospital vs outpatient observation.

2. Document consideration of laparoscopy or laparotomy if intrauterine pregnancy is unlikely bases on this evaluation.

3. Laparoscopy or laparotomy is indicated with any of the following:

a. Increasing symptoms;
b. Developing mass;

c. Suggestive ultrasound;
d. high index of suspicion.

4. Follow-up care

a. bHCG should be monitored weekly until serum level is negative (should occur within 8 weeks);
b. Low dose prophylaxis, (Microgram), should be considered in an Rh-patient.

References: Precis IV: An Update in Obstetrics and Gynecology, Gynecology Section, Medical Specialty Advisory Committee, Maine Demonstration Project

VII. CONDITION: Singleton Breech Presentation

A. When the presence of a breech presentation is identified, the patient.

B. Cesarean section is currently the most common method for delivery in breech presentation unless delivery is imminent.

C. When a vaginal breech delivery is considered, the physician should inform patient as to which method of delivery is considered best on the basis of the clinical situation and the circumstances of support facilities and personnel.

D. Facilities should include the capability of emergency Cesarean section.

E. The physician must have experience with vaginal breech delivery.

F. Anesthesia personnel should be present for delivery.

G. Presentation should be that of a frank breech. Any other presentation requires further evaluation.

H. The fetal weight should be estimated at less than 4,000 gm.

I. Hyperextension or macrocephaly should be ruled out by clinical examination or appropriate diagnostic imaging.

J. Pelvic size should be adequate and is usually determined by pelvimetry, clinically and/or radiographically.

K. There should be adequate progression of labor in dilation, effacement and descent.

L. Intravenous lines along with facilities for maternal surgery and transfusion should be in place.

M. Fetal heart monitoring is required.

N. Local, pudendal, regional and general anesthesia are all used in breech presentation deliveries.

O. Parity does not effect the route of delivery.

References: ACOG technical bulletin #95 - August, 1986; Precis IV, An Update in Obstetrics and Gynecology: 150-151, 1990; Clinical Standards for Obstetrics Services of Harvard Medical Institutions: #19

VIII. CONDITION: Perinatal Herpes Simplex Virus Infections

A. Confirmation of Diagnosis:

1. Characteristic visible lesions;
2. Immunofluorescent test or culture if available.

B. Management:

1. If there are no visible lesion at the onset of labor, vaginal delivery is acceptable.

2. Weekly surveillance cultures of pregnant women with a history of HSV infection, but no visible lesions, are not necessary and vaginal delivery is acceptable.

3. Amniocentesis in an attempt to rule out intrauterine infection is not recommended for mothers with HSV infection at any stage of gestation.

4. Term patients who have visible lesions and are in labor or who have ruptured membranes should undergo Cesarean delivery.

5. For patients with active HSV infections and premature rupture of membranes remote from term, there is not enough data to recommend a management protocol that would apply in all clinical situations. The risk of extreme prematurity must be weighed against the risk of neonatal HSV infection. The patient should be encouraged to take an active role in this decision.

6. Monitoring by fetal scalp electrode is not contraindicated if needed to adequately asses the fetal condition in women with a history of HSV infection but without lesions or symptoms.

7. Every effort should be made to avoid direct contact with herpetic lesions by the newborn.

8. Mothers with visible HSV infections should be allowed to breast-feed, providing there are no visible lesions in the regions of the breasts and she has been counseled regarding the possibility of spreading the virus by direct contact.

Reference: ACOG technical bulletin #122 - November 1988

IX. CONDITION: Intrapartum Fetal Distress

A. Introduction:

The goal of Intrapartum Fetal Heart Rate (FHR) Monitoring is to detect signs that warn of potential adverse fetal events in time to permit intervention. Another way to state this is that intrapartum fetal heart rate monitoring tries to identify fetal distress in its early stages. While fetal distress is a widely used term, it is poorly defined in the medical literature. This document will define fetal distress, using a combination of national medical literature and local (State of Maine) definitions.

B. Definitions:

1. Variable deceleration: Decreases in FHR from the baseline rate that are non-uniform periodic changes that bear little relationship to uterine contractions. Onset may come at any phase of the contraction, and the wave form is usually different from that of the uterine contraction.

2. Severe variable deceleration: FHR of less than 70 beats per minute (b.p.m.) that persists longer than 60 seconds duration.

3. Persistent severe variable deceleration: Severe variable decelerations that persists for longer than 30 minutes.

4. Late deceleration: Decrease in FHR from the baseline rate with a lag time of greater than 20 seconds from the peak of the contraction to the nadir of FHR deceleration.

5. Persistent and nonremediable late deceleration: Late decelerations that do not respond to the usual obstetrical interventions and occur repeatedly over a 10-15 minute time period.

6. Severe bradycardia: FHR less than 80 b.p.m.

7. Persistent severe bradycardia: Severe bradycardia that persists for longer than 5 minutes.

C. Confirmation of Diagnosis:

For a diagnosis of fetal distress to be made, the presence of one or more of the following must be present:

1. Persistent severe variable deceleration.

2. Persistent and nonremediable late decelerations.

3. Persistent severe bradycardia.

D. The following actions should have been performed and documented prior to expediting delivery for fetal distress.

1. Reposition patient.

2. Administer oxygen by mask.

3. Perform vaginal examination to check for prolapsed cord.

4. Ensure that qualified personnel are in attendance for resuscitation and care of the newborn.**

**Each institution shall define in writing the term qualified personnel for resuscitation and care of the newborn.

E. The following actions should be performed and documented prior to starting a Cesarean section for fetal distress.

1. Perform vaginal exam to rule out imminent vaginal delivery.

2. Initiate preoperative routines.

3. Monitor fetal heart tones (by continuous fetal monitoring or by auscultation) immediately prior to preparation of the abdomen.

4. Ensure that qualified personnel are in attendance for resuscitation and care of the newborn.**

**Each institution shall define in writing the term qualified personnel for resuscitation and care of the newborn.

F. When a diagnosis of fetal distress is made, consideration should be given to performing:

1. Umbilical cord acid-base studies.

2. Pathologic examination of the placenta.

References:

1. ACOG Technical Bulletin: Intrapartum Fetal Heart Rate Monitoring. #132 - September 1989.

2. Quality Assurance in Obstetrics and Gynecology: ACOG Obstetrical Criteria Status, Cesarean Delivery for Fetal Distress. May 1989, p. 23.

3. Danforth's Obstetrics and Gynecology 6th Edition. Chapter 16 Clinical Evaluation of Fetal Status. Intrapartum Fetal Monitoring, pp. 319-327 c.1990.

4. Obstetric, Neonatal, and Gynecologic Care (A Practical Approach for the Indian Health Service) 5th Edition, 1989.

5. Manual of Obstetrics, Diagnosis and Therapy: 3rd edition, Chapter 24, Fetal Heart Rate Monitoring, pp. 301-314.

6. Parer and Livingston, What Is Fetal Distress: AM. J. OBSTET. GYNECOL, 1990; 162: 1421-7.

7. Classification of Fetal Patterns from Dr. Albert D. Haverhamp, M.D.: City and Country of Denver, Department of Health and Hospitals: Handout for House officers, 1979.

8. Obstetrical Pearls: A Practical Guide For the Efficient Resident, Care of the Laboring Patient, Fetal Monitoring pp. 45-50. c.1989.

X. CONDITION: Anterpartum Management of Prolonged Pregnancy

A. Introduction:

The accurate determination of the time of conception is extremely important in reducing the false diagnosis of post-term pregnancy and in precisely ascertaining the point at which a pregnancy becomes high risk. The expected date of confinement (EDC) is most reliably and accurately determined early in pregnancy. Consistency between historical and physical data is important in establishing the reliability of dating.

B. Definitions:

1. Prolonged Pregnancy is pregnancy that lasts greater than 287 days (41 completed weeks) from the first day of the last menstrual period.

2. Post-term Pregnancy is a pregnancy that lasts greater than 294 days (42 completed weeks) from the first day of the last menstrual period.

3. Criteria for confirming gestational age should

include 2 of the following in addition to a complete menstrual history.

a. Fetal heart tones have been documented by 20 weeks gestation by non-electronic fetoscope or by 13 weeks gestation by electronic fetoscope;
b. Uterine size has been established by pelvic examination prior to 16 weeks of gestation;
c. A positive serum or urine human chorionic gonadotropin (hCG) pregnancy test was present 6 weeks after the last normal menstrual period;
d. Ultrasound.
   (1) Measurement based on the "crown-rump length" obtained between 6 and 12 weeks of gestation, or
   (2) Measurement based on the "biparietal diameter" obtained between 14 and 26 weeks of gestation.

4. Gestational age cannot be accurately determined by using the criteria in #3 if the patient presents at 22 weeks gestation or later.

C. Action:

1. At 41 weeks gestation (+2 days), the patient should have a nonstress test (NST). If reactive, the practitioner may elect to continue to follow the pregnancy.

2. Between 41-42 weeks gestation, the patient should have an ultrasound to evaluate adequacy of amniotic fluid. Results of the ultrasound need to be available within 24 hours. If determined to be adequate, the practitioner may elect to continue to follow the pregnancy.

3. Between 42-43 weeks gestation, the patient should have two (2) nonstress tests (NST) performed. The first should be performed approximately one (1) week after the nonstress test at 41 weeks gestation and the second should be performed three to four (3-4) days after the first. If reactive, the practitioner may elect to continue to follow the pregnancy.

4. Ultrasound evaluation of the adequacy of amniotic fluid should be completed at weekly intervals after the initial ultrasound completed at 41-42 weeks. Results of the ultrasound need to be available within 24 hours. If determined to be adequate, the practitioner may elect to continue to follow the pregnancy.

5. If possible, ultrasound exams performed at 41 weeks gestation and beyond should contain a report on the estimated fetal weight.

6. At 43 weeks gestation, the patient should be delivered.

7. Contraction stress tests (CST) can be substituted for nonstress tests (NST) in the above actions.

8. Biophysical profiles can be substituted for ultrasound exams in the above actions.

D. Contraindications to the Proceeding Protocol:

Patients with the following diagnoses/problem should have individual treatment plans.

1. Gestational Diabetes.

2. Hypertension in Pregnancy.

3. Macrosomic Infant.

4. Intrauterine Growth Retardation.

5. Previous History of Fetal Demise.

6. Fetus with uncertain gestational age and/or prenatal care starting at or after 22 weeks gestation.

References:

1. ACOG Technical Bulletin, Number 130, July 1989, pp. 1-4.

2. Clinical Standards for the Obstetrical Services of the Harvard Medical Institutions, Dec. 1, 1988.

3. Alfared W. Brown, Jr. and Robert C. Cefalo, eds, Guidelines for Prenatal Care, 2nd ed., (Evanston, Illinois: American Academy of Pediatrics/American College of Obstetricians and Gynecologists, 1988). p. 66. Language contained within parentheses reflects local modifications to the source document.

4. Eastern Maine Medical Center Family Practice Residency Program Protocol for the Prevention and Management of Postdates Pregnancy, January 1990.