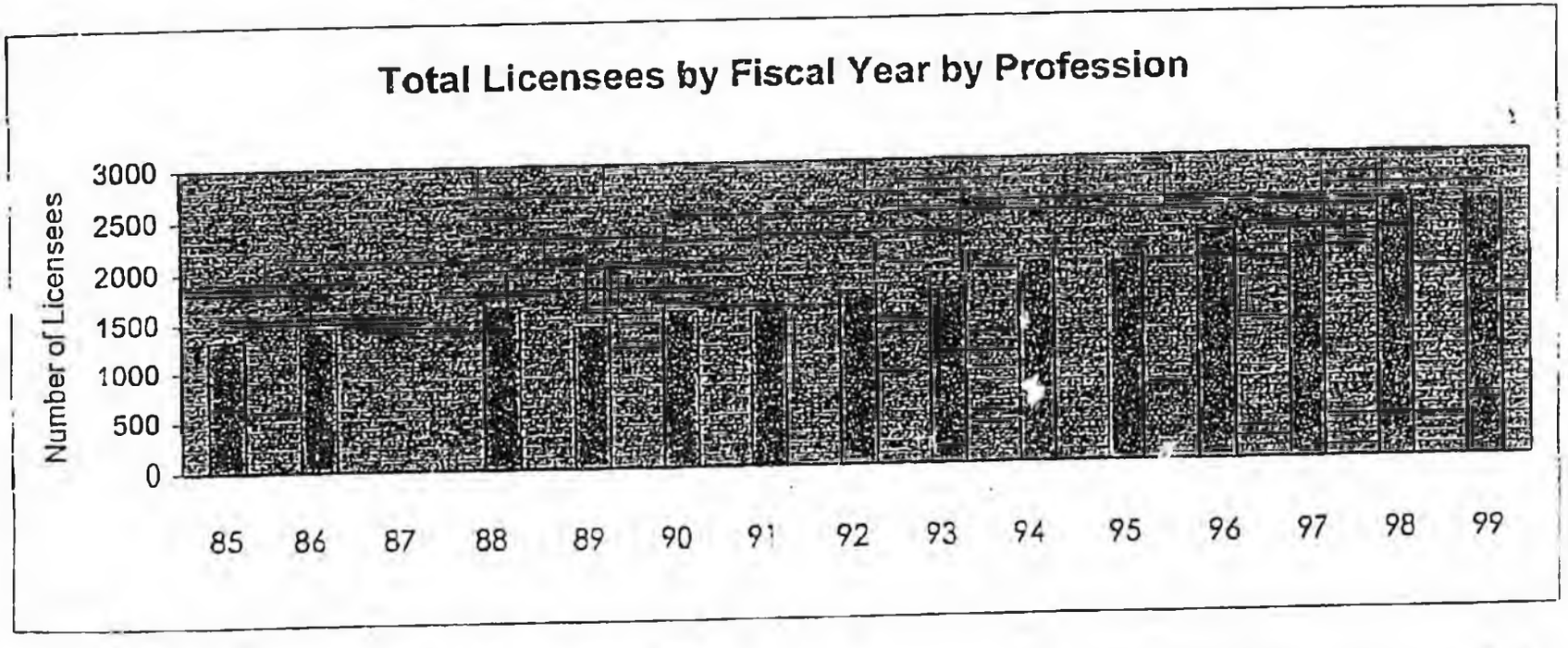
ALASKA LEGISLATURE COMMITTEE FILES 1999-2000 8672
10061 SENATE HEALTH EDUCATION & SOCIAL SERVICES

	FY 85	FY 86	FY 87*	FY 88	FY 89	FY 90	FY 91	FY 92	FY 93	FY 94	FY 95	FY 96	FY 97	FY 98	FY 99
MD/DO Active	815	934	0	1089	925	1038	1004	1152	1183	1417	1419	1593	1603	1826	1810
MD/DO Inactive	317	305	0	322	255	254	273	263	243	243	262	262	277	266	300
DPM-Act/Inact	0	11	0	0	0	0	9	11	12	15	13	14	14	15	15
PA-C	111	111	0	126	136	157	159	186	177	216	200	231	221	255	244
MICP	76	85	0	91	100	111	106	119	112	135	134	158	151	191	195
TOTAL	1321	1446	0	1628	1418	1560	1553	1731	1727	2026	2028	2258	2266	2553	2564

* Statistics not available for 1987.



MD means Medical Doctor (Allopathic)
DO means Doctor of Osteopathy
DPM means Doctor of Podiatric Medicine

PA means Physician Assistant - Certified
MICP means Mobile Invensive Care Paramedic

CORRECTION

THE FOLLOWING DOCUMENT(S)
HAVE BEEN REFILMED TO
ASSURE LEGIBILITY OR PAGINATION

	FY 85	FY 86	FY 87*	FY 88	FY 89	FY 90	FY 91	FY 92	FY 93	FY 94	FY 95	FY 96	FY 97	FY 98	FY 99
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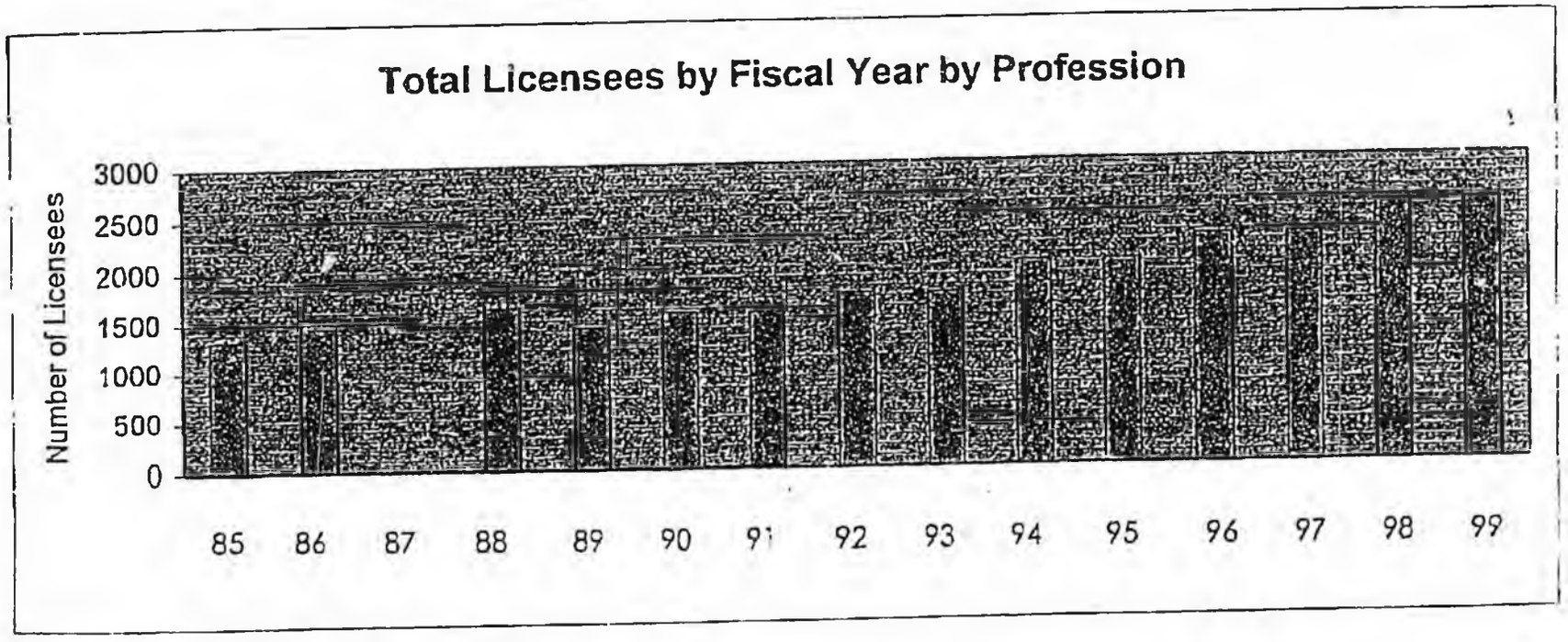

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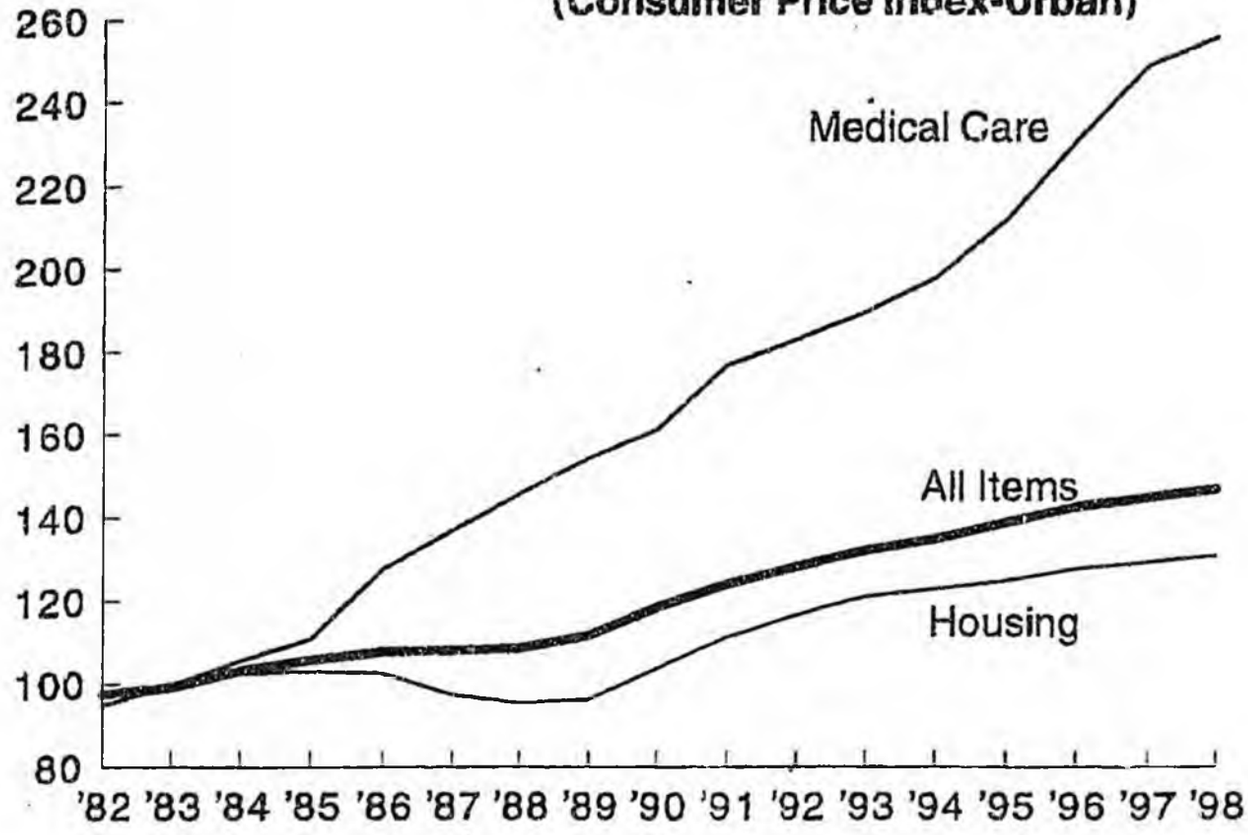
Medical Costs Outpace Housing

In Anchorage—(CPI-U)

(Consumer Price Index-Urban)



Source: U.S. Department of Labor, Bureau of Labor Statistics

Alaska State Medical Association

4107 Laurel Street • Anchorage, Alaska 99508 • (907) 562-0304 • (907) 561-2063 (fax)

February 18, 2000

Honorable Mike Miller
State of Alaska
Senate
State Capital, Room 119
Juneau, Alaska 99801-1182

RE: SB 256–"Fairness in Health Care Contracting"

Dear Senator Miller:

The Alaska State Medical Association (ASMA) represents Alaska's patients and the physicians who care for them. Thank you for this opportunity to testify on SB 256. It was ASMA, among other organizations, that represent physicians that sought the introduction of this bill.

Attached you will find a copy of a sectional analysis of SB 256. In this analysis you will see that ASMA strongly supports the enactment of this measure. However, several amendments are suggested. The major amendment would be to have this act apply to all types of health plans and not just those insured by health care insurers in Alaska. This suggestion would mean that physicians would also be allowed to jointly negotiate with large self-insured plans as well. (ASMA has already had discussion about this matter with Senator Kelly's staff prior to the introduction of SB 256).

SB 256 would create a more fair and equitable negotiating process between doctors and the large and powerful insurance companies. This is not a measure that would allow doctors to strike or engage in any boycott of services.

ASMA urges you to support SB 256 with the amendments suggested.

Sincerely,

Peter Lawrason

BY: Peter Lawrason, MD, President

FOR: Alaska State Medical Association

cc: Sen. Pete Kelly

JJJ/kms

Senate Bill 256
"Fairness in Health Care Contracting"
Sectional Analysis

Section 1

This section adds those provisions of any physician services contract that are either required or currently prohibited. The purpose, theoretically, for this section is to provide consistency with the provisions of HB 211 (Regulation of Managed Care) pertaining to physician services agreements. By including this section, the same requirements are in place for physician services contracts arrived at through joint negotiations.

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> "(4) clearly states the rate and method of compensation for each group managed care health plan for which the health care provider is to provide health care services for the covered persons;"

It is expected and desired to have SB 256 amended so that it covers negotiations with self-insured groups as well. When this happens, it is suggested that Section 1 not be in the form it currently is in. Those provisions in Section 1 should be included in a section under AS23.50. Perhaps, they could be included in AS23.50.025 a new section titled "Contract Provisions". The change in this "lead in" language could be changed to reflect the all inclusiveness (insured and self-insured plans) desired by using the term "health benefit plan" instead of the term "managed care entity". The term "health benefit plan" is defined in AS21.54.500 (15) and appears to include both insured and self-insured plans. (Other editorial changes would need to be made to reflect this change as well.)

Section 2

AS23.50.010

AS23.50.010 articulates the reasons for the Legislature to set policy to allow joint negations between a group of competing physicians and a health insurance company.

AS23.50.020

AS23.50.020 (a) enumerates those items which may be the subject of joint negotiations. Those items include clinical practice guidelines and coverage criteria; respective liability of physicians and health care insurers; administrative procedures that include methods and timing of payments to physicians; resolution despute procedures; patient referral procedures; application of the reimbursement methodologies to be used; quality assurance programs; utilization review procedures; and criteria for the selection and termination of participating physicians. Note that this subsection does not allow for negotiation of fees or payments. AS21.050.020 (b) prohibits joint negotiation for those fee or payment related items unless the conditions of AS21.050.020 (c) are met.

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The exception is made to allow for joint negotiation for those fee items listed in AS21.050.020 (b) when a health insurer has "substantial market power". AS21.050.020 (c) defines substantial market power when an insurer has more than 15% of the market place as measured by the number of people covered. Included in the numbers of people covered are those covered under Medicare and Medicaid if an insurer provides any claim payment services for the government for those programs. The concept is based in that all "bodies" covered and threats of not contracting with a certain physician are based on the deleterious effect on a physician's practice by removing those patents from his/her practice. Enumerating the persons covered may be difficult for the Division of Insurance. In fact, it is impossible for the Division of Insurance to compel self-insureds to provide it with those data. In one state currently addressing the State Action Doctrine exception issue (California), it is being considered to just require all health plans to negotiate with physicians without having to prove the "substantial market power" percentage. (Obviously this would allow physicians to still jointly negotiate and under active state oversight). The reason for this is that it is clear in California that less than 10 health plans dominate its market place. It is perceived that less than 6 health plans dominate Alaska's marketplace. One suggestion would be to make the negotiations a requirement but with a "rebuttable presumption" that a particular health insurer could make that it does not have "substantial market power" as defined as a market share that exceeds 15%.

AS21.050 (d) sets out the criteria for how those collective rights are to be carried out by the physicians jointly negotiating. The core provision is that negotiations are to be conducted through an "authorized third party" who will negotiate on behalf of the physicians who have joined together for that purpose. Conceivably,

that person acting as the authorized third party representative could be an IPA, a lawyer, a physician, a specialty medical society, a local medical association, a state medical association, etc. It is presumed a contractual relationship will exist between the represented physicians and the authorized third party that memorializes the obligations and requirements of the parties. This subsection states that the physicians who have joined for the purpose of negotiation may communicate with their authorized third party about terms and conditions, which are to be negotiated. The authorized third party is the sole person who is to negotiate on behalf of the doctors. Subsection (5) of this section may provide some confusion in that it would appear to defeat the purpose of the joint negotiations. The intent of subsection (5) is to provide, for example, for different rates of reimbursement to be included for different specialties. (For example, anesthesiologists are typically reimbursed in a different manner than a surgeon and both may be in the same group of physicians engaged in joint negotiations.) Generally, an authorized third party may not represent more than 30% of the physicians in a particular geographic area. However, if an insurer or health plan has 5% or more market penetration in a geographic area, then an authorized third party may represent more than 30% of the physicians. Obviously, the concern would be that physicians represented in great numbers would dictate the terms of a contract to an insurer or health plan. By the same token, for example, it would be unfair for a specialist, who is the only one in a particular area, not be able to join with other physicians to jointly negotiate. This is an area that active state oversight would be necessary so that a fair result for the general public would be the outcome.

AS21.050.020 (e) sets out what a person desiring to act as an authorized third party needs to do in order to act in that capacity. In short, the authorized third party needs to register with the Commissioner of Labor and Workforce Development. That registration requires an identification of the authorized third party and how that person intends to operate. It is presumed that this would include a detailed plan of operation along with the contract that it has entered into with the group of physicians to be represented. This must be done for each physician service contract that the authorized third party wishes to jointly negotiate on behalf of the physicians represented. The efficiencies or benefits that are expected to be achieved must be identified. The authorized third party is required to report to the Commissioner of Labor if a health care insurer or health plan declines to negotiate or terminates a negotiation within 14 days of receiving that decision. Also, if an insurer or health plan fails to respond within 14 days of a request for negotiation, that fast also needs to be reported to the Commissioner.

AS21.050.020 (f) requires the Commissioner, with the advice of the Attorney General, to either approve or disapprove a negotiated contract within 30 days of when it is presented. If it is disapproved, the Commissioner must give a written explanation of the deficiencies and how they could be corrected.

AS21.050.020 (g) prohibits the physicians represented from acting together in response to a report from their authorized third party regarding its discussion or negotiation with a health care insurer or health plan. The authorized third party has a duty to warn the physicians represented of the potential of legal action under state and federal anti-trust laws for exceeding the authority granted by this measure.

AS21.050.020 (h) limits the terms of any contract negotiated to 5 years. It is expected that terms of actual contracts will be for less than 5 years.

AS21.050.020 (i) keeps all documents relating to joint negotiations, that would come from both the physicians and insurers or health plans, confidential and not subject to public inspection.

AS23.50.030

AS23.50.030 creates a fee mechanism to cover the State's cost of providing its active oversight of the joint negotiation authorized by this bill. The fee is to be reflective of the actual costs that the State incurs. The Commissioner sets the fees by regulation and must report on the fees each year to the Office of Management and Budget. At least one other state in dealing with a "State Action Doctrine" exception (California) charges the regulatory costs to the health care insurers and health plans on a pro-rata share based on their market share. Theoretically, the cost should be the same without regard to who pays it. If the physicians pay it via their authorized third party, then they will negotiate sufficient payment levels to cover that cost. Conversely, if the insurers and health plans pay it, then they will negotiate a sufficiently lower payment level to cover that cost. The issue is what is the most efficient and fair method to cover the cost. Obviously, the physician community will not be supportive of a fee mechanism that requires a payment upfront only to have an insurer decline to negotiate and not receive any refund.

AS23.50.040

AS23.50.040 allows the Commissioner of Labor and Workforce Development to adopt regulations to implement this law.

AS23.50.099

AS23.50.099 is the definition section and contains the definition of the terms "authorized third party", "commissioner", and "health care insurer". These definitions are straightforward and unambiguous. This section will be expanded if the SB 256 is amended to also include self-insured health plans. For example, the term "health benefit plan" would need to be defined as it is in AS 21.54.500 (15).

Section 3

This section is needed to provide for joint negotiation by physicians under the "State Action Doctrine" exemption under Alaska's laws pertaining to competitive practices and regulation of competition.

JJJ/kms

TESTIMONY ON SENATE BILL 256
ALASKA SENATE HESS COMMITTEE

February 21, 2000

My name is Gordon Evans and I represent the Health Insurance Association of America ("HIAA"), which is a trade association of the nation's leading commercial health insurance companies which provide health insurance for approximately 55 million Americans.

Thank you, Mr. Chairman, for providing an opportunity to present HIAA's position on Senate Bill 256. HIAA opposes SB 256 for two simple reasons -- first, giving physicians an antitrust waiver would deny consumers choice, quality, and affordability; and second, health care costs would increase significantly for both the public and private sectors.

In the past year, there has been significant debate at both the federal and state level about physician collective bargaining or physician antitrust waivers. Despite differences among the various proposals, there are four incontrovertible facts:

* Quality is not the driving force behind the physician collective bargaining movement -- it's economics. Legitimate mechanisms already exist within the boundaries of current antitrust law under which health care providers can and do collaborate and negotiate with health plans, patients, and others on clinical or quality of care issues or other concerns they may have regarding the impact of managed care on the quality of care.

* Second -- Consolidation among health plans has been and continues to be subject to rigorous antitrust scrutiny, at both the state and federal levels.

* Third -- Antitrust waiver legislation is anti-competitive and would raise costs for health care programs financed by both the public and private sectors -- through Medicare, Medicaid, and other government programs, as well as employer- and union-sponsored plans.

* Fourth -- Legislation at either the state or federal levels will be costly. For example, if legislation such as that proposed at the federal level (H.R. 1304 by Congressman Campbell) were to become law, health care premiums in the private sector would increase by 6 to 11 percent. Total annual personal health care spending would rise up to $80 billion annually. These added costs would be paid for by consumers, employers, and taxpayers, without any improvement in the quality of patient care. Or, at least 1.2 to 2.4 million more Americans would be uninsured.

Physicians, who are already among the nation's highest paid professionals, are among the least likely Americans to need the benefits of unionization. Over the last decade, as managed care has grown, physician incomes have increased more than 77 percent, with a median net income in 1997 of $199,600. Antitrust waivers or some other form of the special treatment that they are seeking through Senate Bill 256, would effectively allow physicians to further increase their salaries.

Moreover, the reality is that physicians are not seeking to form real unions. Rather, they seek to form unrestricted collective bargaining units without the regulatory oversight that all unions are subject to.

Physicians are asking state and federal governments for unique legal rights to engage in conduct that would otherwise be *per se* illegal under the antitrust laws. Granting physicians, whether as physician employees or as independent contractors, special waivers to collectively bargain and set prices, without regulatory oversight fundamental to the very concept of unionization, is unwarranted, not to mention detrimental to consumers.

Physician collective bargaining legislation is opposed by the chairman of the Federal Trade Commission, Robert Pitofsky, who says that conferring a labor exemption on physicians "would merely grant them broad immunity to present a 'unified front' when negotiating price and other terms of dealing with health plans, without any efficiency benefits for consumers or any regulatory oversight to safeguard the public interest."

Much has been made of the growth and consolidation of managed care organizations. In fact, physicians cite this as one of the reasons why they need antitrust waivers. Under current law, consolidation among health plans and insurers is subject to rigorous antitrust scrutiny at both the state and federal levels.

The health insurance industry continues to remain very competitive, making it improbable -- if not impossible -- for any one plan to be able to exercise significant market power in its negotiations with health care providers.

In conclusion, Mr. Chairman, collective bargaining for physicians truly would serve to benefit the few at the expense of consumers and taxpayers. It would level a devastating blow to the health care system and the success that market competition has achieved in limiting health-care inflation.

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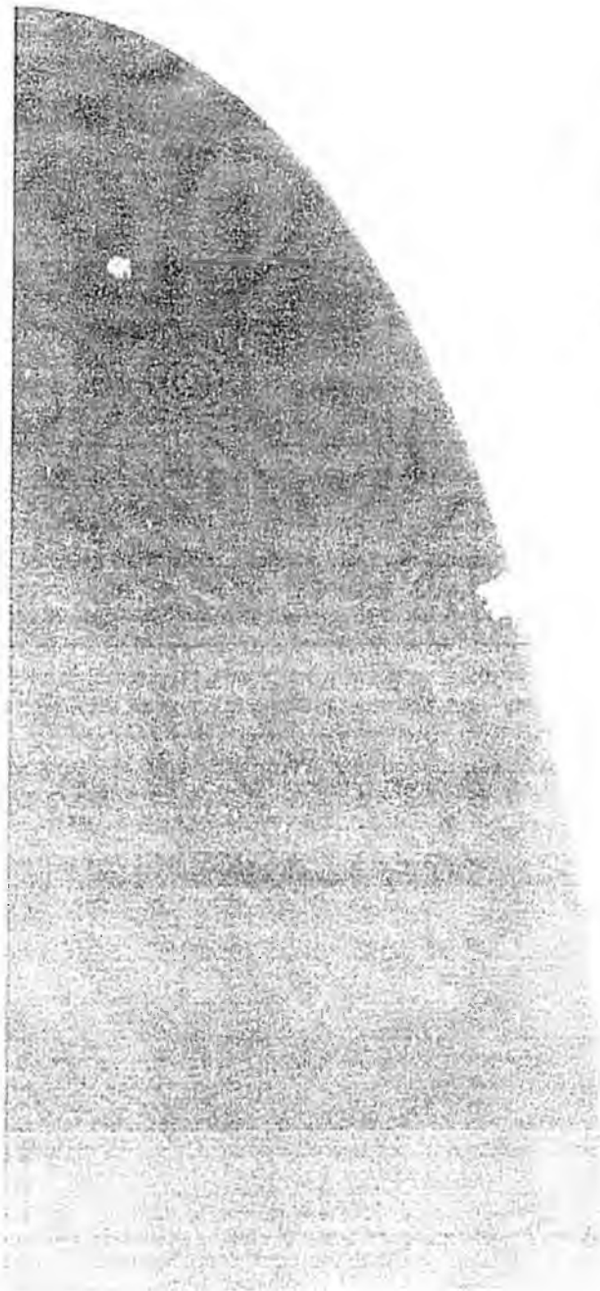
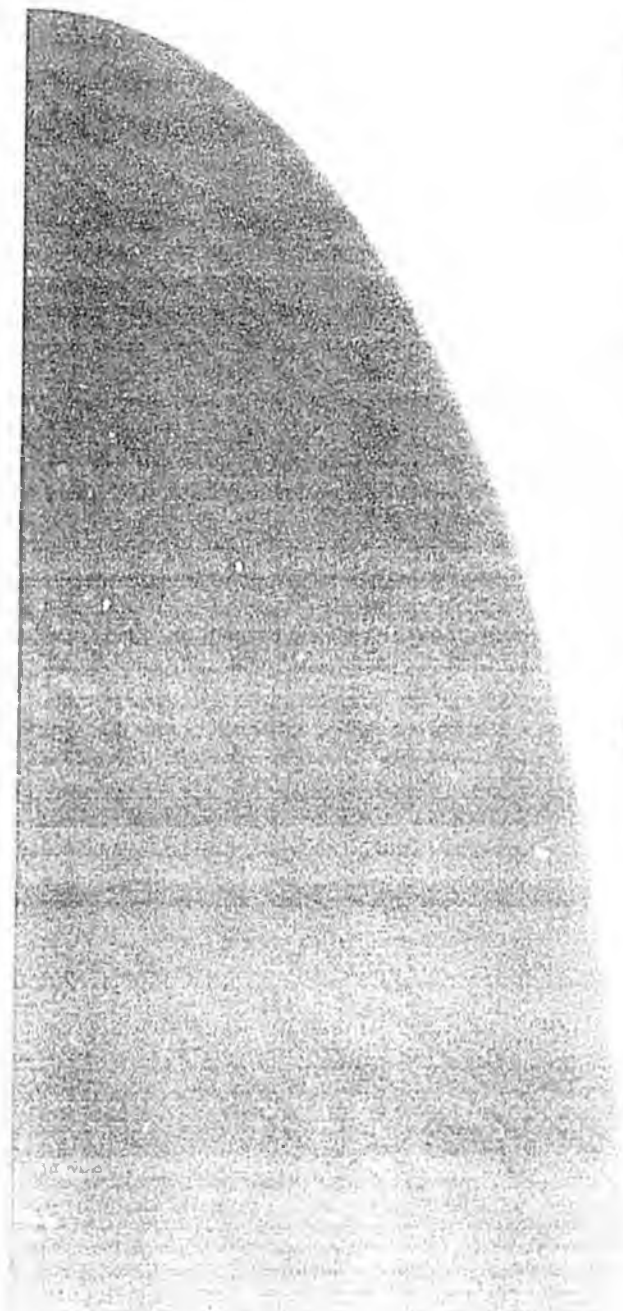


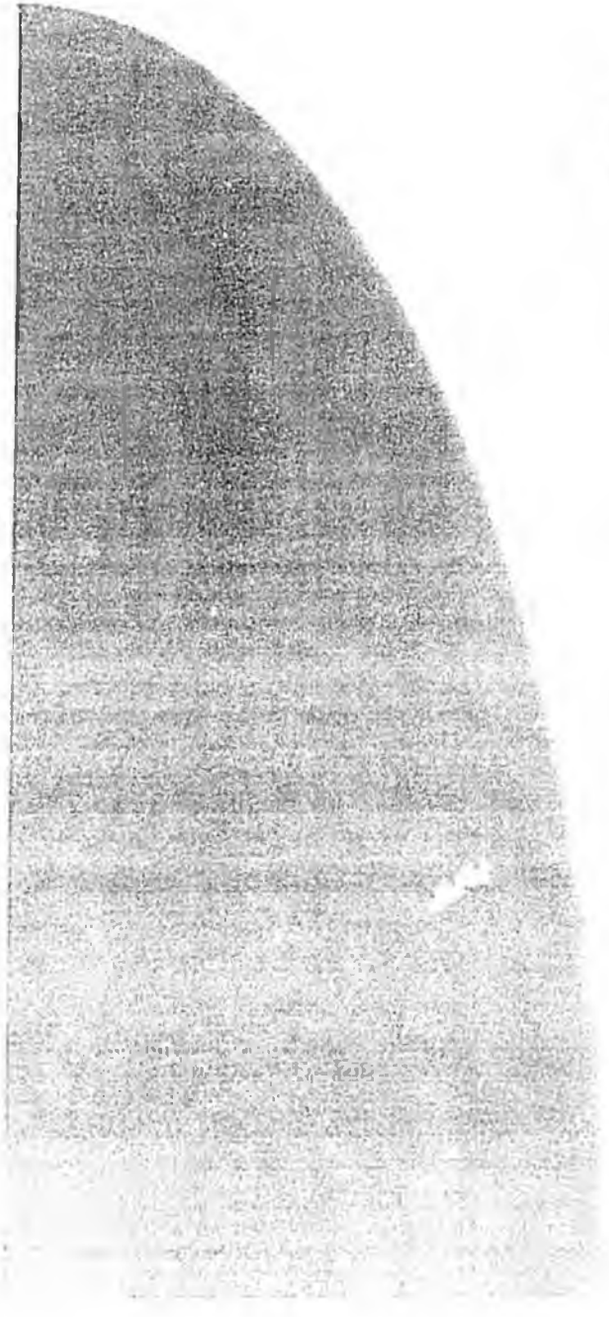
Issue

- SB256 is intended to address perceived inequities in bargaining power between physicians and insurers in Alaska. From our perspective this inequity does not exist.



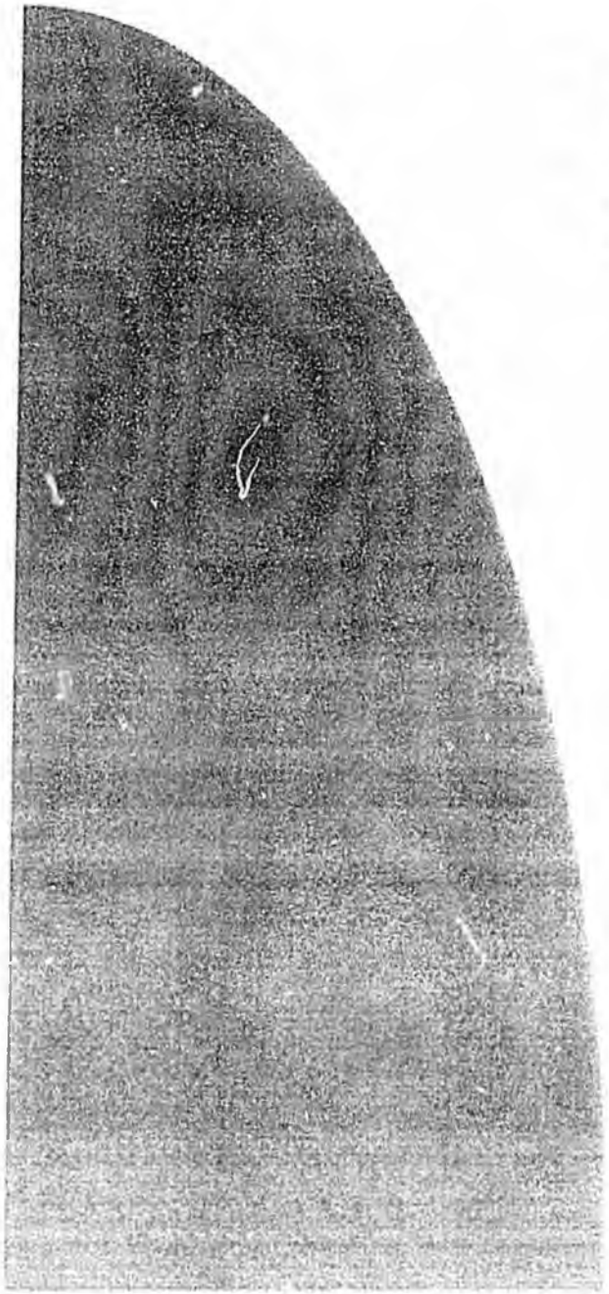
What evidence supports our perspective?

- The Results of 11 years of negotiations in AK
- The Terms of the contracts being offered in AK
- The contracting Process in AK



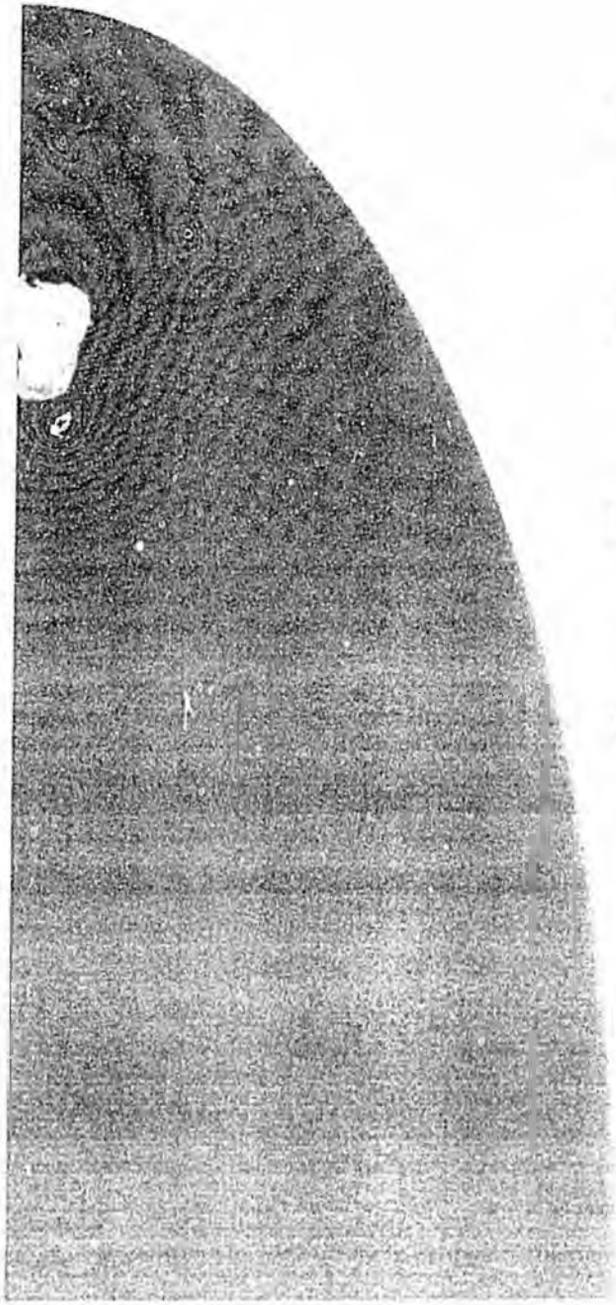
Results after 11 years:

- Approximately 1700 physicians in AK
- Blue Cross Blue Shield of Alaska has approximately 700 agreements
- Aetna, after repeated attempts, approximately 100 agreements
- Other Insurers, virtually no physician contracts



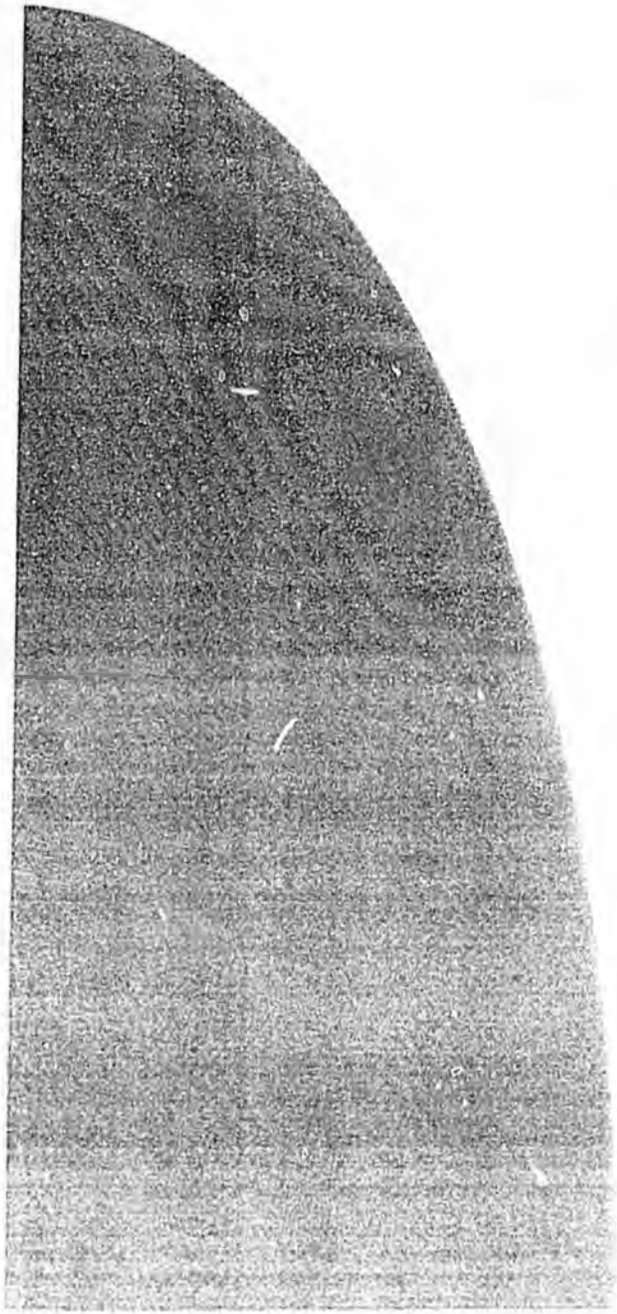
Results: Examples of specialty "holes"

- Anchorage: Gastroenterology, Otolaryngology, Cardiovascular Surgery, Colon and Rectal Surgery, Plastic Surgery
- Fairbanks: Medical Oncology, Plastic Surgery, Urology
- Juneau: Otolaryngology, Pediatrics, Neurosurgery, Plastic Surgery



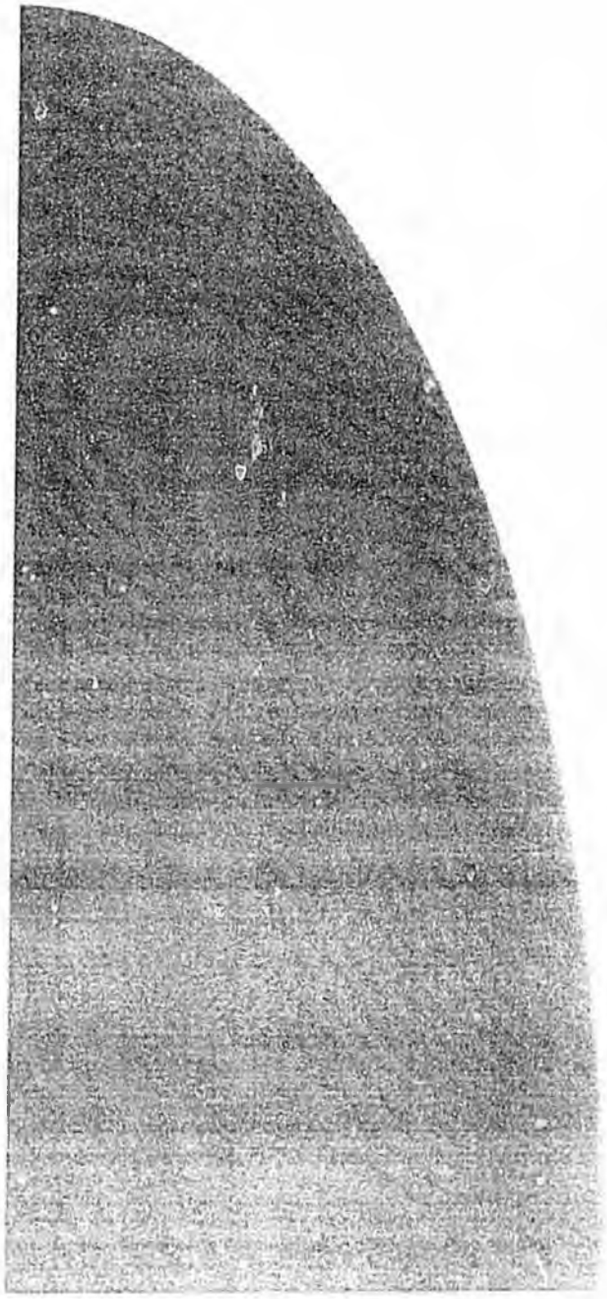
The Terms:

- Physician bill BCBSAK directly: not the member
- BCBSAK pays the physician directly: not the member
- Physician submits to credentially process: additional member protection
- Physician cooperates with Care Management program



The Terms continued:

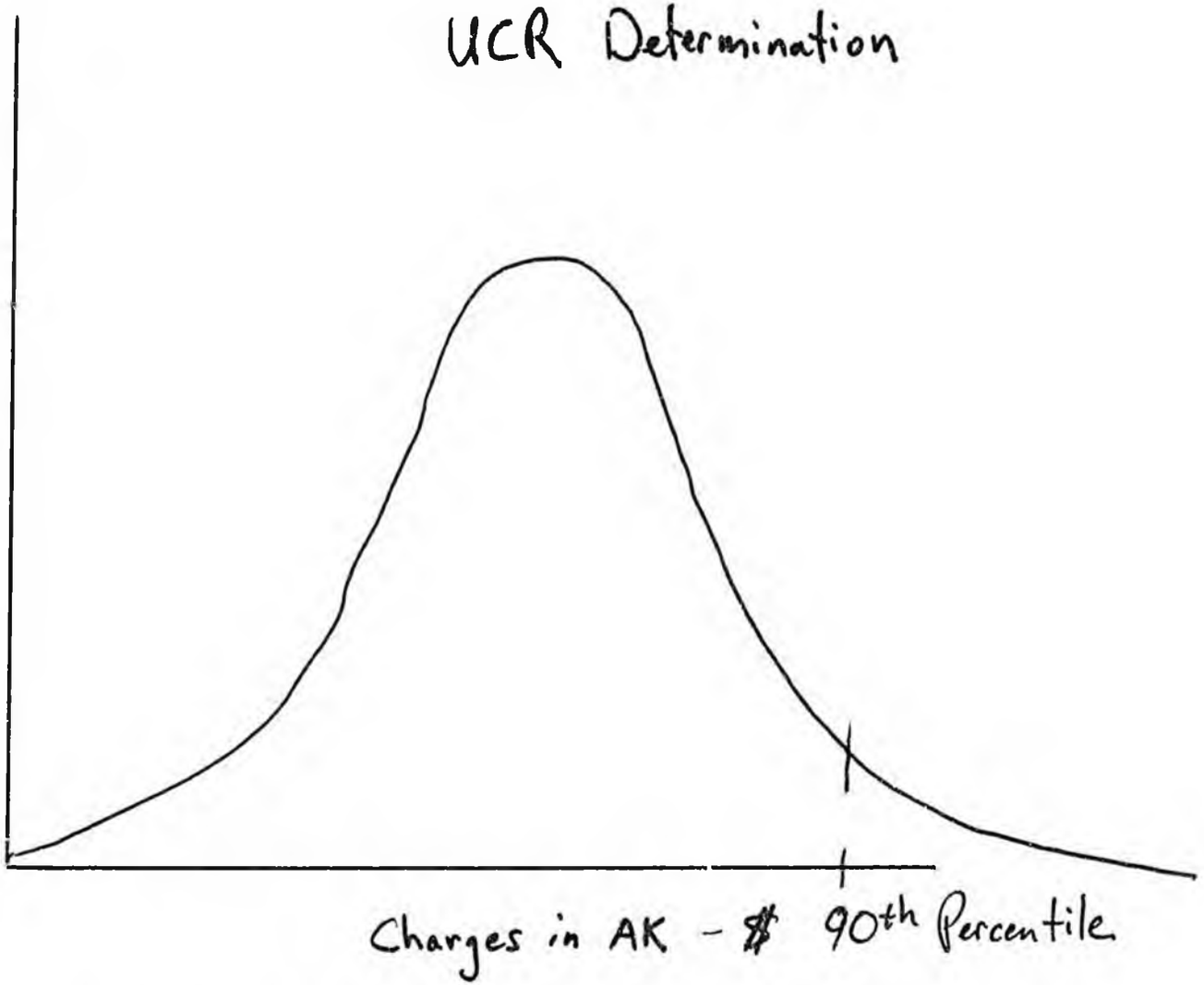
- Physician agrees to refer to network providers: "The Provider will admit or arrange for admission of Preferred Enrollees only to Preferred Hospitals provided that one is locally available and, **in the professional judgement of the Provider**, admission to or treatment at the Preferred hospital **will adequately provide the enrollee's medical care needs**."



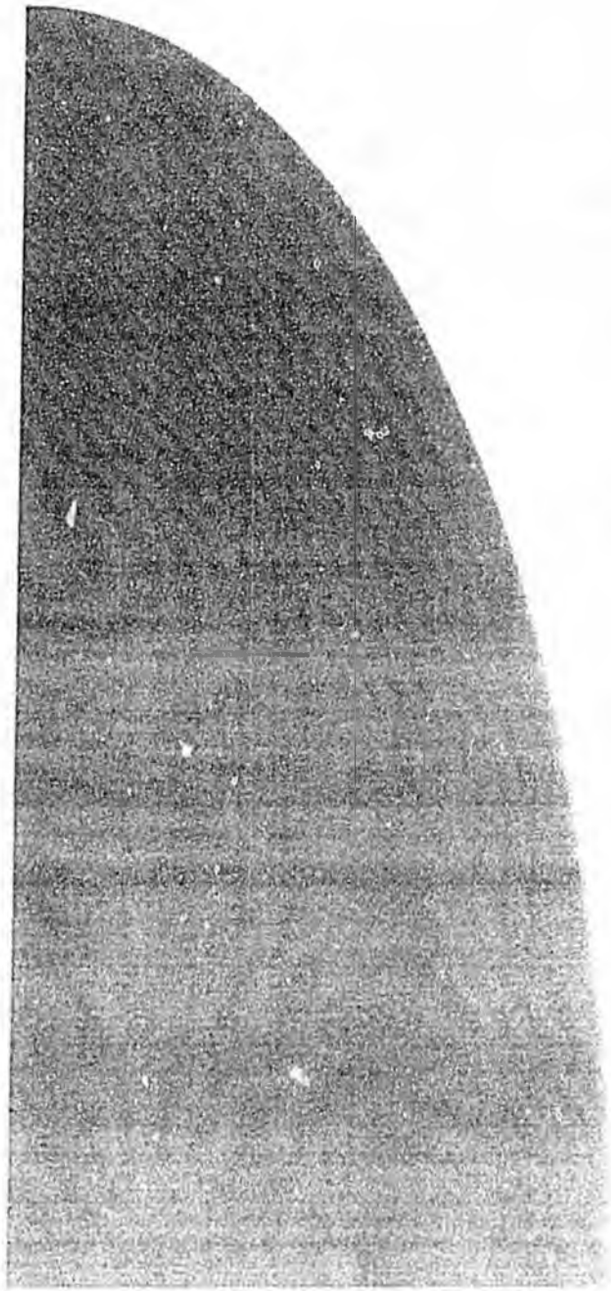
The Terms continued:

- Physician agrees not to bill member for amounts, if any, which exceed Usual, Reasonable and Customary charges.
- Termination by either party without cause with 30 days notice
- Above are standard terms. Many physicians have **negotiated** special terms.

UCR Determination



+ According to AK statute
+ 12 months of data, updated every 6 months
+ Subject to review by Division of Insurance



How does reimbursement work?

- If charge below the 90th percentile, full charge allowed.
- If charge at or above the 90th percentile, 90th percentile allowed.
- Physician agrees not to bill member for amounts over 90th percentile.

Example A: Charge less than UCR

UCR = $120
Charge = $100
"Allowed = $100
Coinsurance = 80%
Plan Payment = $80
Member pays = $100 - 80 = $20

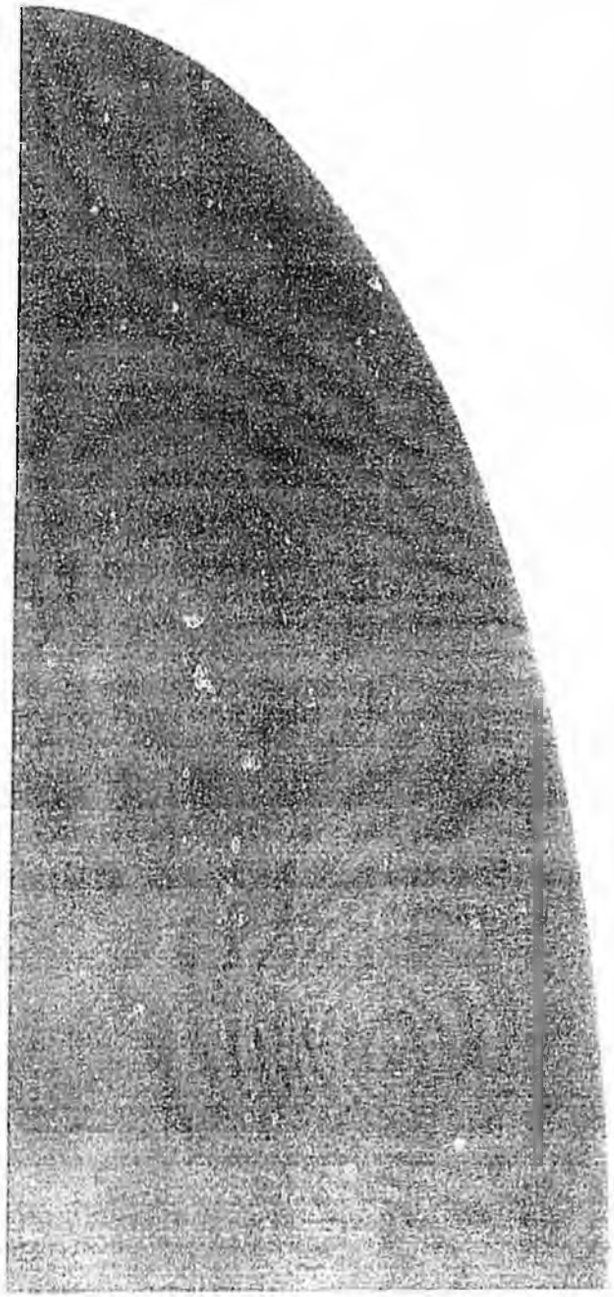
Example B: Charge more than UCR

UCR = $200
Charge = $220
Allowed = $200
Coinsurance = 80%
Plan Payment = $160

If contracted physician:
Member pays = $200 - $160 = $40

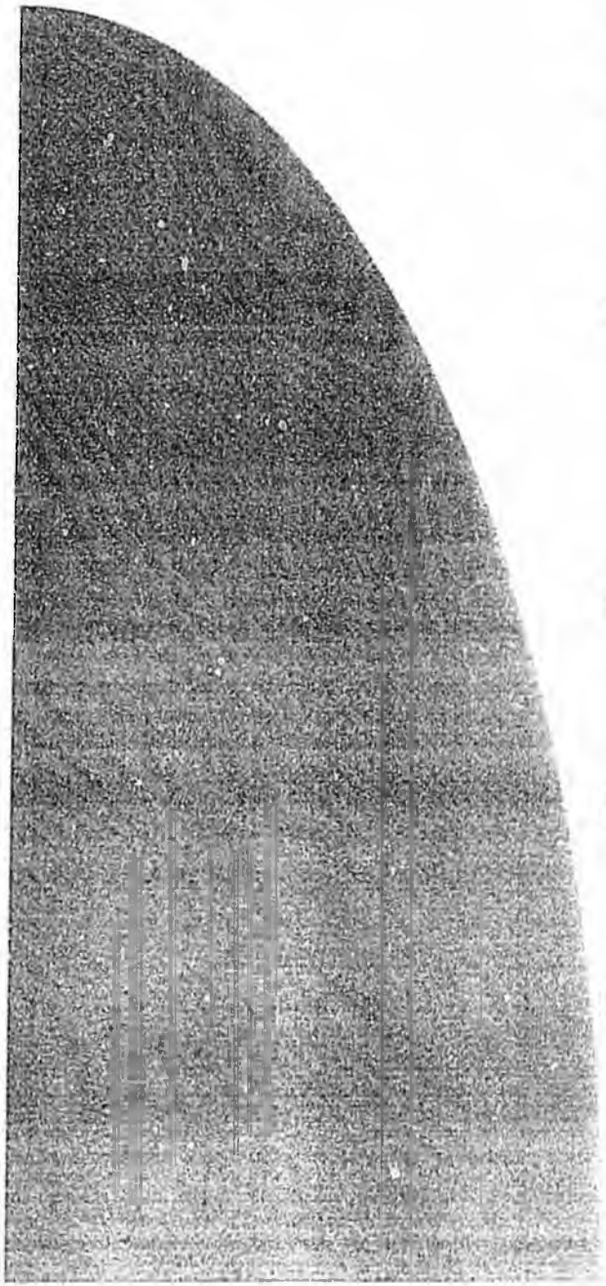
If physician not contracted:
Member pays = $220 - 160 = $60

Contract protects Member from amounts over UCR/Allowable



The Process:

- We identify physicians for discussion
  - Member requests
  - "holes" in network
- Often physicians contact us
- Make contact; information for consideration
  - Not interested - 33
  - Wish more information - 91
  - Agreement reached - 15



Federal Employee Program:

- Rules determined by Federal Office of Personnel Management in Baltimore
- BCBSAK required to administer according to Federal rules
- If contracted, reimbursed 95% or AK UCR
- If not contracted, reimbursed 75% of Medicare rates

Alaska State Legislature
Senator Pete Kelly

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Interim
119 N. Cushman St. Suite 201
Fairbanks, AK 99701
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Senate Bill 256

An Act relating to regulation of managed health care and allowing physicians to collectively negotiate with a health care insurer that has substantial market power

Senate Bill 256 attempts to level the playing field for Alaska's patients and the physicians who care for them.

In a perfect world, equal bargaining power would exist between the medical care providers and the health insurers. Big hospitals have more equal bargaining power with the health insurers than the typical Alaskan physician in a solo or small group practice. Obviously, a gross inequity in bargaining power exists and there is no conceivable way any health insurer will bargain with an individual doctor regarding individual contract provisions other than on a take it or leave it basis. The resultant effect is physician service contracts heavily weighted in favor of the insurance company. The bottom line is that, in many respects, this adversely affects the care that patients receive. For example, requiring a physician to use a lower cost treatment when a higher cost treatment may be medically necessary or preventing a physician from discussing alternative treatments.

Independent, competing physicians are prevented from any collective action by the federal anti-trust laws to which, ironically, the insurers are not subject. This fact plus the market concentration of health insurers causes the imbalance in bargaining power. With insurers having such a high degree of leverage, a balance of interest no longer exists in the market for health care delivery and finance.

Senate Bill 256 can permit independent, competing physicians to collectively negotiate with health insurers in regard to the provisions of physician services contracts to provide quality health care to Alaskans. When the provisions set forth in SB 256 are met, behavior that would otherwise violate the anti-trust laws will be exempt from antitrust scrutiny. The test for qualifying exemption varies depending on the identity of the party performing the action in question. But SB 256 will still prohibit a group of independent competing physicians from striking or otherwise engaging in activities that would result in a boycott.

Senate Bill 256
"Fairness in Health Care Contracting"
Sectional Analysis

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AS23.50.020 (a) enumerates those items which may be the subject of joint negotiations. Those items include clinical practice guidelines and coverage criteria; respective liability of physicians and health care insurers; administrative procedures that include methods and timing of payments to physicians; resolution despute procedures; patient referral procedures; application of the reimbursement methodologies to be used; quality assurance programs; utilization review procedures; and criteria for the selection and termination of participating physicians. Note that this subsection does not allow for negotiation of fees or payments. AS21.050.020 (b) prohibits joint negotiation for those fee or payment related items unless the conditions of AS21.050.020 (c) are met.

AS21.050.020 (b) prohibits joint negotiations involving fees or prices for services; the conversion factor in a RBRVS type payment methodology; amounts of discount on the physician's services; and dollar amounts for a "capitation" basis of payment. However, it still allows physicians to jointly and collectively petitions the government for a change in law that provides for payment to doctors under a governmental program (e.g., Medicaid).

The exception is made to allow for joint negotiation for those fee items listed in AS21.050.020 (b) when a health insurer has "substantial market power". AS21.050.020 (c) defines substantial market power when an insurer has more than 15% of the market place as measured by the number of people covered. Included in the numbers of people covered are those covered under Medicare and Medicaid if an insurer provides any claim payment services for the government for those programs. The concept is based in that all "bodies" covered and threats of not contracting with a certain physician are based on the deleterious effect on a physician's practice by removing those patents from his/her practice. Enumerating the persons covered may be difficult for the Division of Insurance. In fact, it is impossible for the Division of Insurance to compel self-insureds to provide it with those data. In one state currently addressing the State Action Doctrine exception issue (California), it is being considered to just require all health plans to negotiate with physicians without having to prove the "substantial market power" percentage. (Obviously this would allow physicians to still jointly negotiate and under active state oversight). The reason for this is that it is clear in California that less than 10 health plans dominate its market place. It is perceived that less than 6 health plans dominate Alaska's marketplace. One suggestion would be to make the negotiations a requirement but with a "rebuttable presumption" that a particular health insurer could make that it does not have "substantial market power" as defined as a market share that exceeds 15%.

AS21.050 (d) sets out the criteria for how those collective rights are to be carried out by the physicians jointly negotiating. The core provision is that negotiations are to be conducted through an "authorized third party" who will negotiate on behalf of the physicians who have joined together for that purpose. Conceivably,

that person acting as the authorized third party representative could be an IPA, a lawyer, a physician, a specialty medical society, a local medical association, a state medical association, etc. It is presumed a contractual relationship will exist between the represented physicians and the authorized third party that memorializes the obligations and requirements of the parties. This subsection states that the physicians who have joined for the purpose of negotiation may communicate with their authorized third party about terms and conditions, which are to be negotiated. The authorized third party is the sole person who is to negotiate on behalf of the doctors. Subsection (5) of this section may provide some confusion in that it would appear to defeat the purpose of the joint negotiations. The intent of subsection (5) is to provide, for example, for different rates of reimbursement to be included for different specialties. (For example, anesthesiologists are typically reimbursed in a different manner than a surgeon and both may be in the same group of physicians engaged in joint negotiations.) Generally, an authorized third party may not represent more than 30% of the physicians in a particular geographic area. However, if an insurer or health plan has 5% or more market penetration in a geographic area, then an authorized third party may represent more than 30% of the physicians. Obviously, the concern would be that physicians represented in great numbers would dictate the terms of a contract to an insurer or health plan. By the same token, for example, it would be unfair for a specialist, who is the only one in a particular area, not be able to join with other physicians to jointly negotiate. This is an area that active state oversight would be necessary so that a fair result for the general public would be the outcome.

AS21.050.020 (e) sets out what a person desiring to act as an authorized third party needs to do in order to act in that capacity. In short, the authorized third party needs to register with the Commissioner of Labor and Workforce Development. That registration requires an identification of the authorized third party and how that person intends to operate. It is presumed that this would include a detailed plan of operation along with the contract that it has entered into with the group of physicians to be represented. This must be done for each physician service contract that the authorized third party wishes to jointly negotiate on behalf of the physicians represented. The efficiencies or benefits that are expected to be achieved must be identified. The authorized third party is required to report to the Commissioner of Labor if a health care insurer or health plan declines to negotiate or terminates a negotiation within 14 days of receiving that decision. Also, if an insurer or health plan fails to respond within 14 days of a request for negotiation, that fact also needs to be reported to the Commissioner.

AS21.050.020 (f) requires the Commissioner, with the advice of the Attorney General, to either approve or disapprove a negotiated contract within 30 days of when it is presented. If it is disapproved, the Commissioner must give a written explanation of the deficiencies and how they could be corrected.

AS21.050.020 (g) prohibits the physicians represented from acting together in response to a report from their authorized third party regarding its discussion or negotiation with a health care insurer or health plan. The authorized third party has a duty to warn the physicians represented of the potential of legal action under state and federal anti-trust laws for exceeding the authority granted by this measure.

AS21.050.020 (h) limits the terms of any contract negotiated to 5 years. It is expected that terms of actual contracts will be for less than 5 years.

AS21.050.020 (i) keeps all documents relating to joint negotiations, that would come from both the physicians and insurers or health plans, confidential and not subject to public inspection.

AS23.50.030

AS23.50.030 creates a fee mechanism to cover the State's cost of providing its active oversight of the joint negotiation authorized by this bill. The fee is to be reflective of the actual costs that the State incurs. The Commissioner sets the fees by regulation and must report on the fees each year to the Office of Management and Budget. At least one other state in dealing with a "State Action Doctrine" exception (California) charges the regulatory costs to the health care insurers and health plans on a pro-rata share based on their market share. Theoretically, the cost should be the same without regard to who pays it. If the physicians pay it via their authorized third party, then they will negotiate sufficient payment levels to cover that cost. Conversely, if the insurers and health plans pay it, then they will negotiate a sufficiently lower payment level to cover that cost. The issue is what is the most efficient and fair method to cover the cost. Obviously, the physician community will not be supportive of a fee mechanism that requires a payment upfront only to have an insurer decline to negotiate and not receive any refund.

AS23.50.040

AS23.50.040 allows the Commissioner of Labor and Workforce Development to adopt regulations to implement this law.

AS23.50.099

AS23.50.099 is the definition section and contains the definition of the terms "authorized third party", "commissioner", and "health care insurer". These definitions are straightforward and unambiguous. This section will be expanded if the SB 256 is amended to also include self-insured health plans. For example, the term "health benefit plan" would need to be defined as it is in AS 21.54.500 (15).

Section 3

This section is needed to provide for joint negotiation by physicians under the "State Action Doctrine" exemption under Alaska's laws pertaining to competitive practices and regulation of competition.

JJJ/kms

Antitrust Relief

Egregious Contract Clauses

The Campbell bill would allow physicians to jointly negotiate against such clauses

The "Cheapest" Care

This clause allows the plan to restrict care to the cheapest treatments, not the best or most appropriate for the patient.

> "*Medical necessity* means the SHORTEST, LEAST EXPENSIVE, OR LEAST INTENSE LEVEL of treatment, care or service rendered, or supply provided, as determined by us [health plan], to the extent required to diagnose or treat an injury or sickness. [Emphasis added] (American Medical Security, Inc., plan supervisor and administrator for self-funded employee benefit plan)

The "Fall Guy"

Health plans shift liability to physicians for patient harm caused by the plan's own actions. Taken together these three clauses effectively require physicians to comply with the plan's decisions and policies - that directly affect the quality of patient care - while the plan avoids legal liability for them.

> "Provider agrees to participate in, cooperate with and comply with all decisions rendered in connection with [health plan's] Utilization Management Program..."
>
> "Provider agrees to render Covered Services to Beneficiaries...in accordance with... the clinical quality of care and performance standards that are professionally recognized andor accepted by [health plan]." - not necessarily the physician
>
> "PROVIDER SHALL BE SOLELY RESPONSIBLE for the quality of Covered Services rendered to beneficiaries." [Emphasis added]
>
> (Independence Blue Cross p. 2, Clause 1.13, p.4, Clause 2.2(a), and p.5, Clause 2.7 and 2.10)

Pass The Buck

Health plans shift responsibility to physicians for their own breaches of confidentiality.

> "Provider agrees to defend, hold harmless and indemnify Company and its officers, shareholders, employees, agents and subagents from any and all claims, causes of action, lawsuits, liabilities, damages and expenses ...arising from or relating to any release or disclosure MADE BY COMPANY..." [emphasis added] (Wellmark Blue Cross/Blue Shield of Iowa p. 10, clause 10.4)

The Great "Unknown"

Physicians are forced to agree to terms without knowing what they will be. In this example, the health plan would force a physician to participate in a plan without knowing the type of plan, the rules and procedures, the number of patients, the payment, etc.

> "Company reserves the right to introduce new Plans during the course of this agreement. Provider agrees that Provider will provide covered services to Members of such Plans under applicable compensation arrangements determined by company." (Aetna Specialist Physician Agreement, clause 8.2)

Our Way or the Highway!
Health Plans can unilaterally change the contract terms at any time without physician consent:

> "BLUE CROSS has established a Utilization Review (UR) program which shall seek to assure that Hospital Services or Medical Services provided to Members are Medically Necessary. The Utilization Review shall follow the procedures described on Exhibit C, attached to and made part of this Agreement. BLUE CROSS may change UR procedures by delivering amendments to, or a replacement for, Exhibit C at least thirty (30) days prior to implementation." (Blue Cross of California Prudent Buyer Plan, clause 7.1)

Surprise!
Changes can be made at any time *without notice:*

> "Provider agrees: a) To participate, as requested, and to abide by Company's utilization review, patient management, quality improvement programs, and all other related programs (AS MODIFIED FROM TIME TO TIME) and decisions with respect to all members." (Aetna Specialist Physician Agreement, clause 4.2)

No competition
Health Plans prevent physicians from accepting any new patients from competing health plans.

> "To prevent discrimination against Company or its members, for such time as provider declines to accept new members as patients, provider shall not accept as patients additional members from any other health maintenance organization." (Aetna proposed Primary Care Physician Agreement, paragraph 1.2)

"Lemon Laws"
Health Plans insist upon contracts that do not disclose essential terms- one way is to refuse to disclose reimbursement rates and better yet, retain the right to change them at any time:

> "Company shall ... pay Provider for [services] rendered to Members in accordance with: (a) the THEN-CURRENT Company Reasonable, Equitable Fee Schedule (REF); or (b) the compensation arrangement THEN IN EFFECT as applicable to such Member's Plans; either of which may be modified from time to time by company." [Emphasis added] (Aetna Specialist Physician Agreement, clause 3.1)

Patients - Don't Bother Asking!
Gag practices prevent physicians from discussing treatment options with their patients if there is a chance that the health plan won't pay:

> "Provider shall not provide or threaten to provide inferior care or imply to members that their care or access to care will be inferior due to the source of payment." (Aetna Specialist Physician Agreement p. 2, clause 1.2)

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American Medical Association

Physicians dedicated to the health of America

Memo to: Executive Directors
State Government Affairs Contacts
State Medical Societies
National Medical Specialty Societies

From: Ross N. Rubin, Vice President
Legislative Affairs

Rebecca A. Cerny, Director
Division of State Legislation

Date: February 17, 1999

Subject: AMA Model State Legislation on State Action Doctrine

As you know, one of the main focuses of the Association has been to identify strategies to help physicians achieve greater bargaining leverage against health plans. This is particularly important in the current health care market, where health plans have amassed enough market leverage to virtually dictate the terms of the contracts they offer physicians. To many physicians, the "strength in numbers" derived from coming together to negotiate fees and other contractual terms is the most obvious way to achieve favorable contracts with health plans. The antitrust laws, however, present a major roadblock to physicians, in that they prohibit physicians from coming together to bargain collectively with health plans and other payers.

At the June 1998 meeting, the House of Delegates adopted Resolution 258. Resolution 258 called upon the Association to develop a negotiating unit, within organized medicine and with no affiliation with national trade unions, free of antitrust constraints for all of its members in order to help level the playing field with health care payors. At the December, 1998 meeting, the House adopted Board of Trustees Report 14, which in part calls upon the Association continue to identify ways in which collaboration by physicians can benefit the public and to inform antitrust enforcement agencies of these findings. In addition, Board of Trustees Report 14 asked the Association to examine the feasibility of drafting model state legislation and, if appropriate, draft such legislation for dissemination. *The AMA Council on Legislation considered and approved model state legislation on the state action doctrine at its January 1999 meeting. The AMA Board of Trustees adopted the model state legislation during its February 1999 meeting.*

Enclosed you will find 1) a summary of the state action doctrine as it pertains to collective negotiation among physicians, including a discussion of the Washington state law on this issue, and 2) model state legislation relating to state action doctrine recently approved by the AMA's Board of Trustees. Please feel free to contact Ross Rubin at (312) 464 – 4040 or Rebecca Cerny at (312) 464 – 4503 with any questions you may have.

STATE ACTION DOCTRINE

The American Medical Association has been working to develop a collective bargaining unit, recognized under the National Labor Relations Act (NLRA), to provide a professionally grounded entity for physicians eligible to organize under that Act. The Association is also continuing to support federal legislation to amend the antitrust laws to allow physicians not eligible under the NLRA. It is expected that Representative Campbell will reintroduce his bill soon.

There is, however, an interim step that in some cases can permit independent physicians to negotiate with plans. This step is based on a line of cases that creates a "state-action doctrine" under the antitrust laws. (Parker v. Brown).

Summary of the State Action Doctrine

The state action doctrine was first set forth in a 1943 Supreme Court decision in *Parker v. Brown*. In general, it states that the **antitrust laws do not apply to action by a state operating in its sovereign capacity, or to private conduct compelled or approved by the state. In other words, where the requirements of the state action doctrine are met, behavior that would otherwise violate the antitrust laws will be exempt from antitrust scrutiny.**

The test for qualifying for the exemption varies, depending on the identity of the party performing the action in question:

1. Where the party is a state legislature or a state court, the exemption is complete, and no further inquiry is required;

2. Where the party is a state agency or local government official, further inquiry is required with respect to whether the action in question followed "clearly articulated and affirmatively expressed state policy;" and

3. Where the party is a private party, the test for qualifying for the state action exemption is the strictest. In addition to having to comport with the "clearly articulated and affirmatively expressed state policy" spelled out above; the action must be subject to "active state supervision." In other words, the state must, *in practice*, exercise some degree of independent judgment or control over the activity. Passive or theoretical power of a state to review private action will be insufficient to meet this standard.

Collective Negotiation Among Physicians Under the State Action Doctrine

Independent physicians fall into the category of private party. Therefore, actions taken by physicians that would ordinarily be illegal under the antitrust laws – in this instance, collective negotiation with health plans – will be exempt from antitrust scrutiny ***only to the***

extent that the activity comports with the requirements laid out above in item 3. Specifically, the antitrust laws will not prohibit independent physicians in a particular state from negotiating collectively with health plans where:

- **The relevant state has a "clearly articulated and affirmatively expressed state policy" that permits independent physicians to negotiate collectively with health plans.**

  The most obvious way for a state to lay out this policy is through legislation. If a state has on its books legislation specifically stating that physicians may negotiate collectively with health plans, then the first requirement for the state action exemption will be satisfied. *[It should be noted that the introduction of a bill that permits independent physicians to negotiate collectively with health plans is bound to generate a certain degree of controversy. This is because such legislation will be perceived as opening the door to activity that will have anti-competitive effects that will ultimately harm the consumer. For example, critics of such legislation might argue that allowing independent physicians to negotiate collectively with health plans will benefit physicians by helping them to keep their fees up, but will harm consumers in that higher fees will translate into higher premiums. Critics might also point to the risk of physicians engaging in boycott activity, where the health plans do not respond favorably to the terms and conditions the physicians demand in the course of the collective negotiations. This, too, could have a negative impact on consumers, who might not be able to secure medical services when needed. Consequently, to increase its chance of passage, such legislation must be carefully drafted, pointing out the possible pro-competitive reasons for allowing physicians to negotiate collectively with health plans. It should also contain provisions that provide reassurance to legislators that boycott activity, or other activity that causes direct harm to the consumer, will not qualify for antitrust exemption."*

- **The collective negotiations between physicians and health plans must be subject to "active" state supervision.**

  Although legislation should include a provision that gives a state body the authority to oversee physicians' collective negotiation activity, the mere inclusion of such language in a state statute will not be enough to constitute "active" state supervision. The state body must, in practice, review the negotiations, which might include following certain procedures that give the state body input into the negotiations themselves. A sound way to ensure that a state body has active oversight over the negotiations is to incorporate within the legislation certain duties of the state body in the course of physician negotiations. This way, negotiations can not go forward and be in compliance with the law unless the state body performs certain functions and, hence, is actively involved.

The Washington Example

Before moving directly into possible model legislation, it is helpful first to look at legislation that was passed in Washington state in 1995. This legislation was designed to provide independent physicians with increased negotiating power with health plans. The legislation serves as a good starting point with respect to drafting language that, when implemented, yields a paradigm in which physicians can collectively negotiate with health plans on certain issues without being subject to the antitrust laws. **However, the Washington law has one major shortcoming for our purposes, and that is that it specifically excludes collective negotiation over fees from state action exemption.** Consequently, while model legislation will borrow many of the provisions of the Washington statute, it will reach further to encompass collective negotiations over fees in identified circumstances.

In summary, the provisions of the statute are organized to address the following issues, in order:

1. The policy reasons for permitting collective negotiations in certain circumstances, and for disallowing collective negotiations in others.

2. The terms and conditions over which physicians may collectively negotiate with health plans

3. The terms and conditions over which physicians may not collectively negotiate with health plans

The first three provisions of the statute set forth Washington's "clearly articulated and affirmatively expressed state policy" in favor of collective negotiations between physicians and health plans on specified issues. Therefore, where physicians engage in the practices enumerated by the statutory provisions, they will be exempted from antitrust prosecution, provided the state actively supervises these activities. The remaining statutory provisions institute a formal process involving the state, thereby ensuring that the state is, in practice, actively involved in reviewing collective negotiations conducted by physicians. The provisions address the following issues:

1. The process competing physicians must follow when negotiating with health plans (e.g., physicians must negotiate through a third party they so authorize);

2. The information third parties must supply to the state prior to engaging in collective negotiations on behalf of physicians;

3. The requirement of state approval of the proposed activity as described within the information supplied by the third part representative; and

4. Loss of antitrust exemption as a result of physicians' acting outside of the parameters laid out by the statutory provisions.

Provided Washington physicians act in accordance with the statutory provisions, they will avoid scrutiny under the antitrust laws. However, the statute is actually quite limited with respect to what it allows physicians to do. Most notably, it forbids collective negotiations over fees or price information, and even backs up this prohibition with a policy statement that points to the anti-competitive effects of such practices.

WSMA's Negotiation Service

Following the passage of legislation allowing independent physicians to negotiate collectively with health plans, the Washington State Medical Association (WSMA) developed a negotiation service to assist Washington physicians in conducting such negotiations. The service was set up so that WSMA staff, in conjunction with outside legal counsel, would actually conduct the physicians' negotiations with health plans.

According to John Arveson at WSMA, thus far, the negotiation service has not been used to conduct any negotiations with health plans. When WSMA first announced the availability of the service to Washington physicians, the response was fairly good, with approximately 2400 physicians signing up. However, in light of increasing consolidation among health plans in Washington, the number of physicians signing up to take part in the service did not amount to a critical mass, for the purposes of "making a difference" against area health plans. By way of example, last summer, when one of Washington's largest HMOs offered a contract containing egregious terms and the negotiation service requested to negotiate with the HMO, the HMO declined to negotiate with the physicians.

The events that transpired following the HMO's refusal to negotiate with the physicians suggest that there might be increased demand for the negotiation service in the future. Considering the HMO's contract to be sufficiently egregious, the WSMA presented the contract to the state's insurance commissioner and put together a media campaign against the HMO's contractual practices. The insurance commissioner, who has a reputation for being very pro-consumer, found the contract to be in need of modification. As a result, the HMO is now in negotiations with the insurance commissioner over the terms of the contract. Because the commissioner is "not known to be particularly friendly" to insurance companies, Arveson notes that the next time the HMO is approached by the physicians to negotiate, it will be more open to private negotiations with physicians. Moreover, the media campaign has generated increased physician interest in participating in the negotiation service. Since this summer, WSMA has received an additional 200 to 300 physician applications.

When asked what impact allowing physicians to negotiate on fee-related issues in certain circumstances would likely have on interest in the negotiation service, Arveson said many more physicians would be interested. Therefore, the possibility of including a provision within proposed legislation that permits collective negotiation over fee-related issues in limited circumstances should not be overlooked.

Conclusion

While not a complete solution for independent physicians not eligible to negotiate under the NLRA, pursuit of state legislation to authorize negotiations provides an approach that can be utilized. Such a strategy is not without risk. By operating under the state action doctrine, a certain amount of autonomy will be lost, in that the state will now be involved in the negotiating process. State medical societies will have to weigh the benefits of the antitrust exemption under the state action doctrine against the risks of active state involvement.

MYTHS ABOUT PHYSICIAN NEGOTIATION
(SB1468/HB3039)

MYTH: *Doctors can form groups to negotiate now.*

FACTS:

1) Currently, physician organization is expensive, complex, and often not logistically possible.
2) Organization makes the physician sacrifice his professional option and **deprives patients of choice** of delivery setting.
3) If physicians organize there is no legitimate means to determine if the group is organized in a manner which meets FTC requirements for negotiation. Moreover, the costs of obtaining a legal opinion that can't provide any guarantees can easily run into six figures even before the group is functional.
4) Even if the group does meet FTC standards it doesn't prevent the plan from threatening the group with an antitrust action, resulting in six figure legal fees and the achievement of the plan's ultimate goal—ceasing physician negotiations.

MYTH: *The Federal Trade Commission and the Department of Justice are "easing up" on enforcement and investigation of physician networking and other initiatives.*

FACT:

At their recent joint report to the American Health Lawyers Association, the FTC and DOJ made it clear that physician mergers and other activities continue to be high on their enforcement agenda this year. For example, to show how nearly impossible it is to understand and/or comply with the law, their staff noted that if a physician merger includes the best physicians in the community (the "must haves"), it might be anti-competitive for this fact alone, even if physician organization doesn't have what the enforcement agencies traditionally consider "market power."

MYTH: *This is the first step in a plan by the AMA to unionize physicians.*

FACTS:

1) The AMA has plans to represent those physicians who are eligible to unionize today without the passage of SB 1468 under the National Labor Relations Act (NLRA). These physicians must be employed physicians, and the negotiations must be with their employer. **Texas has a prohibition of the corporate practice of medicine.** Therefore, Texas would not serve as a model for the AMA's ability to represent physicians in NLRA recognized negotiations with employers.
2) This has to do with the ability of physicians to engage in meaningful contract negotiations with very powerful, monopsonistic forces. This is about a **balance of power in the marketplace** and has nothing to do with unionizing.
3) This bill amends the insurance code and deals only with negotiations between physicians and managed care plans. Furthermore, the bill **specifically prohibits strikes and boycotts or any other tactic that would result in denial of patient care.** The AMA and TMA both believe that it is unethical to strike or otherwise use patients as a bargaining chip.

MYTH: *This bill is anti-competitive and such negotiations should be left to the two equally matched, sophisticated parties.*

FACTS:

1) These plans offer a "take it or leave it" approach. **Contracts are non-negotiable.** Furthermore, some plans control as much as 60% of the market. With this kind of market power, physicians have no ability to negotiate.

2) When physician networks do fully integrate and evolve into an entity that can wield some power in the market, the health plan refuses to negotiate with the network and begins to break it apart into individual physicians who can again be bullied into accepting one-sided contracts. A recent memo from Aetna U.S. Healthcare in California contained the following language: ***"In order to participate directly in <u>All</u> Aetna U.S. Healthcare products you will need to withdraw your affiliation with any/all Aetna U.S. Healthcare contracted IPAs and Medicaid Groups."***

MYTH: *These matters should be left to the "free market."*

FACT:
Sure, managed care companies say "free market" when they virtually own the market and have vast anti-trust protections which no other industry enjoys.

MYTH: *This bill will allow physicians to "price fix" and will increase health care costs.*

FACT:
This bill **does not allow physicians to discuss fees unless given specific permission by the Attorney General** to do so. In order for fees to be part of negotiations, the plan must have substantial market power. The AG must also consider the number of physicians involved in fee negotiations relative to the total number of physicians available in the geographic area. **There is no evidence that this bill will increase costs.** The thrust of this bill – and its clear language – is obviously directed to non-fee related, patient care issues.

MYTH: *This bill will increase the number of uninsured at a time when Texas has the dubious distinction of having the largest percentage of uninsured in the country.*

FACTS:

1) Health plans have used this argument over and over again to try to defeat every significant reform measure at the state and federal level. This is transparently self-serving and especially ironic because as managed care has grown, so has the number of uninsured.

2) Once again, the argument is smokescreen. As noted, the issue is irrelevant because any discussion on fees is limited to circumstances where the plan has substantial market power (as determined by the state).

3) Health plans have never been able to demonstrate cost increases specifically related to any managed care reforms.

4) In addition, health plans have not been able to substantiate their claims that small increases in cost result in loss of insurance coverage.

Managed Care Freedom of Choice Act
HB 3039/SB 1468

Question: Why should the Legislature pass this bill?
Answer: Managed care plans are merging at an alarming rate. These mergers are creating huge, powerful health plans that refuse to negotiate with physicians regarding onerous contract provisions. These "take it or leave it" contracts have requirements that can have direct impact on patient care. When physicians attempt to form networks that are large enough to oppose unreasonable contract provisions, the health plans threaten them with bringing an antitrust action. This is becoming a common ploy, not only in Texas, but in other states as well. This bill will give physicians limited protection from such threats when they attempt to negotiate for the removal of contract provisions that can interfere with patients' access to care.

Question: How can a state bill offer any protection from federal anti-trust laws?
Answer: Under a 1943 Supreme Court ruling, *Parker v. Brown*, states can supercede federal antitrust law if there is "a clearly articulated state policy," and "active state supervision." In general, the ruling states that the antitrust laws do not apply to action by the state operating in its sovereign capacity, or to private conduct compelled or approved by the state. In other words, where the requirements of the state action doctrine are met, behavior that would otherwise violate the antitrust laws will be exempt from antirust scrutiny.

Question: Will this bill allow physicians to strike or boycott?
Answer: No! In fact, such activities are specifically prohibited.

Question: Will the passage of this bill drive up health care costs by giving physicians the ability to set fees and other reimbursement rates?
Answer: No! This bill does not allow physicians to "price fix." Physicians may meet and discuss contract provisions only in most situations. These provisions include items like referral requirements, drugs to be included in formularies, access to certain kinds of specialty care for the plan's enrollees, utilization review criteria, etc. Fees can be discussed only in situations where the health plan has substantial market power in a specified geographic area. Substantial market power will be determined by the Attorney General.

Question: Will the physicians be able to act together and agree to accept or reject a health plans offer?
Answer: Yes. However, the plan is free to make offers to physicians individually as well. Physicians may not act in concert with the intent to fix prices, boycott, or otherwise have an unfair advantage over the health plan. Such actions would not be protected from antitrust actions.

Question: If physicians can't negotiate price in most cases, what advantage does this bill give them over what they are currently able to do?
Answer: In today's market, physicians are not allowed to even meet and discuss contracts without threat of an anti-trust action. This means that multi-billion dollar corporations with full time legal staffs present 80 page contracts to solo and small group practitioners. These doctors must retain legal advice just to understand what is included in the contracts. This advice often does not include the impact on patient care that some provisions can have. The doctors have no idea what should be eliminated or amended, and even if they did, the health plan will not make changes at the request of one or two physicians. When a health plan controls 30% or more of a market, it doesn't have to deal with individual doctors. This bill will allow physicians to join together to be represented by a knowledgeable individual who can facilitate discussions about the impact of various contract provisions. It will allow doctors to talk to one another, to educate one another, and to express concerns to the health plan as a group. When acting in accordance with the provisions of this act, the physicians cannot be threatened with an antitrust action.

Question: How does the state "supervise" these activities in order to meet the requirements under *Parker v. Brown*?
Answer: The physicians' representative will file a plan of operation with the Attorney General. The plan will include information on the representative, the physicians to be represented, the health plan with which negotiations will occur and the items for discussion. When the plan makes an offer to the physicians' representative, it will be filed with the Attorney General. The offer must be approved by the Attorney General before it is presented to the physicians.

Question: How will this bill improve patient care?
Answer: Contract provisions that impede the ability of physicians to advocate for their patients must be challenged. Unless there is a balance of power between huge, powerful managed care plans and physicians who care for patients, abusive managed care organizations will continue to place profits above patients. Physicians who refuse to cooperate will be driven from the market and patients will lose access to physicians. Diminished access delays care and decreases choice for every patient.

Legislative Proposal
"State Action Doctrine"

Alaska has never had a great number of health insurance companies competing in the market place. The prospect of even fewer players exists not only here but nationwide. On January 13, 1999, the New York Times reported that since 1994 the leading 18 health insurance companies have combined into 6. As further evidence of this phenomena, if the proposed merger of Aetna/U.S. Health Care and Prudential takes place, the entity created would cover one in every 10 Americans and potentially even a larger number of Alaskans.

Health insurance plans have increasingly incorporated practices and procedures to manage health care in order to keep costs down. One mechanism used is for a health insurer to contract with different types of providers of health care to provide care for its insureds. Theoretically, the health insurer negotiates discounted fees for health care for the promise of a more guaranteed stream of patients.

In a perfect world, equal bargaining power would exist between the medical care providers and the health insurers. Large group medical practices (none of which exist in Alaska) and big hospitals have more equal bargaining power with the health insurers than the typical Alaskan physician in a solo or small group practice. Obviously, a gross in-equity in bargaining power exists and there is no conceivable way any health insurer will bargain with an individual doctor regarding individual contract provisions other than on a take it or leave it basis. The resultant effect is physician service contracts heavily weighted in the favor of the insurance company. The bottom line is that, in many respects, this adversely affects the care that patients receive. For example, requiring a physician to use a lower cost treatment when a higher cost treatment may be medically necessary or preventing a physician from discussing alternative treatments.

Independent, competing physicians are prevented from any collective action by the federal anti-trust laws to which, ironically, the insurers are not subject. This fact plus the market concentration of health insurers causes the imbalance in bargaining power. With insurers having such a high degree of leverage, a balance of interest no longer exists in the market for health care delivery and finance.

A mechanism, however, is available that can permit independent, competing physicians to collectively negotiate with health insurers in regard to the provisions of physician services contracts. That mechanism is an act of the legislature which would create a "state action doctrine" which was first set forth in a 1943 U.S. Supreme Court decision in Parker v. Brown. In general, the state action doctrine states that the anti-trust actions do not apply to actions by a state operating in its sovereign capacity, or to private conduct compelled or approved by the state In other words, where the requirements of the state action doctrine are met, behavior that would otherwise violate the anti-trust laws will be exempt from antitrust scrutiny. The test for qualifying for exemption varies depending on the identity of the party performing the action in question.

If the party is a state legislature or a state court, the exemption is complete and no further inquiry is required. Where the party is a state agency or local government official, further inquiry is required

with respect to whether the action in question followed a "clearly articulated and affirmatively expressed state policy." However, when the party is a private party, the test for qualifying for the state action exemption is the strictest. In addition to having to comport with the "clearly articulated and affirmatively expressed state policy," the action must also be subject to active state supervision. In other words, the state must, in practice, exercise some degree of independent judgement or control over the activity in question. Passive or theoretical power of a state to review a private action in question is insufficient to meet this standard.

Physicians fall into the category of private party. Therefore, collective actions taken by physicians would ordinarily be illegal under anti-trust laws. In the instance of independent, competitive physicians engaging in collective negotiations with a health insurer, such actions would only be exempt from anti-trust scrutiny if the requirements above for a private party are met.

The most obvious way for a state to lay out those requirements is through legislation. Attached is a draft of a bill that lays out the "clearly articulated and affirmatively expressed state policy" and provides for active state supervision through oversight by the Commissioner of the Department of Labor and the Attorney General. Important to note is that this bill will still prohibit a group of independent competing physicians from striking or otherwise engaging in activities that would result in a boycott.

On behalf of Alaska's patients, we ask that you please introduce a bill that comports with the draft bill provided. Please help level the playing field for Alaska's patients and the physicians who care for them.

Alaska Physicians & Surgeons, Inc.
4120 Laurel Street, Ste. 206
Anchorage, Alaska 99508
Phone: 907-561-7705 Fax: 907-561-7704
E-mail: akphys@alaska.net

February 15, 2000

Dear Senator Pete Kelly:

Thank you for the opportunity to provide you and your colleagues with this written statement on why Alaska Physicians & Surgeons (APS) is strongly supporting the passage of SB256. Before I highlight the merits of SB256, I would like to give you some background on APS.

APS is an Anchorage based Independent Practice Association (IPA) formed in 1997. APS now includes over 165 physicians (primary care & specialists). APS' primary goal is to find a solution to what is generally perceived to be the steady encroachment into the practice of medicine by hospitals, 3rd party payors and others. Another important APS goal is to be a more effective advocate for patients. Physicians are without doubt in the best position to understand the medical needs of patients. However, in the recent past there has been a growing disconnect between physicians and patients caused by the current national medical economic delivery models.

In 1998, APS and its board of directors sought legal counsel to ascertain what APS could legally do as a group, and still not run afoul of Federal and State anti-trust prohibitions on communications between independent, competing physicians. The board quickly discovered there was very little they could do when it came to the issue of direct negotiations with 3rd party payors. In fact APS is barred from direct negotiations and is forced to use something called the "messenger model" in contract discussions. APS' messenger can do little more than pass individual physician's opinions on to the carriers and messenger the carrier's response back to the physicians. APS can offer no opinions and the carriers are free to ignore the IPA if they choose, and simply go around us directly to the doctors. This suits the established carriers interests, particularly the largest players in any given market. It is the old rule of divide and conqueror.

The current state of affairs assures a stagnant market, because new carriers find it prohibitively expensive and time consuming to try and penetrate the Alaskan market without assurances they can sign up a significant number of doctors from the start. The most efficient mechanism for these new carriers, is to deal with the doctors through an IPA like APS. If the doctors were allowed to collectively negotiate, new carriers would be much more likely to enter the Alaskan market thereby increasing the competition for patient's health care dollars.

The ultimate question that SB256 addresses is one of simple fairness for patients and physicians. SB256 would provide a mechanism to bring physicians and the larger carriers together to talk about patient and physician protection issues, without the fear on the physicians' part of being sued by the FTC or a private party for violating Federal or State anti-trust law.

The current state of affairs has reached such a low point, that similar legislation is pending at the national level and in numerous states across the country. Currently, doctors in Alaska and nationally feel metaphorically, as though they are forced to sit gagged in small cubicles, isolated from each other and unable to advocate with carriers on behalf of patients.

Let me sum it up by stating that the process outlined in SB256 is voluntary on the part of the carriers, and the state of Alaska would have the obligation and the duty to oversee the process, to ensure both sides comply with the rules.

If you or your staff have any additional questions, please feel free to give me a call at (907) 561-7705.

Sincerely,

Michael Haugen, JD, MBA
Executive Director

SENATE COMMITTEE REPORT
First Committee of Referral

DATE: 2/8/00

FURTHER: Finance

Date of 5-Day Notice: 2/7/00
(in accordance with Uniform Rule 23)

DATE TURNED IN TO OFFICE: 2/24/00

Health, Education and Social Services Committee considered SENATE BILL NO. 256

"An Act relating to regulation of managed health care and allowing physicians to collectively negotiate with a health care insurer that has substantial market power."

and recommends:

[✓] be replaced with ______ CS SB 256 (S) HES)

[ ] adopt previous ______ CS . CS (HES) forthcoming ___(______)

[ ] attached amendment(s)

[ ] adopt Letter of Intent by __________ Committee

[ ] further referral to the __________ Committee

Senate Bill:
[✓] same title
[ ] new title

House Bill:
[ ] same title
[ ] technical title
[ ] new: SCR#_____

SIGNING DO PASS	DP	OTHER RECOMMENDATIONS	NR	DNP	AM
Pete Kelly	✓	Gary Wilken	✓		
		[signature]	✓		
CHAIR:		CHAIR: Pete Kelly	✓		

NEW FISCAL NOTE(S):

Department	Date	Zero	Fiscal
CED	2/22/00		✓

PREVIOUS FISCAL NOTE(S):*

Department	Date	Zero	Fiscal

SB

261

FISCAL NOTE

STATE OF ALASKA
2000 LEGISLATIVE SESSION

BILL NO. SB 261

Revision Date/Time (Note if correction): _____
Dept. Affected: Health and Social Services
Title: Relating to needle stick and sharp injury protections
BRU: State Health Services
Component: Nursing
Sponsor: Elton
COMPONENT SERIAL NO. 288
Requestor: Senate HES
See also (SN#): _____

Expenditures/Revenues: (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below.

OPERATING	FY2001	FY2002	FY2003	FY2004	FY2005	FY2006
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES	43.5	89.2	91.4	93.7	96.0	98.4
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING	43.5	89.2	91.4	93.7	96.0	98.4
CAPITAL EXPENDITURES						
CHANGES IN REVENUES ( )						

FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts						
1003 GF Match						
1004 GF	30.5	62.4	64.0	65.6	67.2	68.9
1005 GF/Program Receipts						
1037 GF/Mental Health	13.0	26.8	27.4	28.1	28.8	29.5
Other (please specify)						
TOTAL	43.5	89.2	91.4	93.7	96.0	98.4

Estimate of any current year (FY2000) cost: $0.0

POSITIONS:

FULL-TIME						
PART-TIME						
TEMPORARY						

ANALYSIS: (Attach a separate page if necessary)

The projected costs were calculated by comparing the costs of stardard syringes and collections tubes with protective devices for the costs which would have been incurred in FY1999 based on that year's actual usage. A factor of 2.5% was built-in for subsequent years to cover increased costs in supplies and growth of the number of people using the Public Health Centers. FY2001 is for 1/2 year as the effective date of the bill is January 1, 2001. There is no cost saving to be corrected for in terms of fewer needlestick incidents to investigate. In SFY99 only one incident occurred and the cost per incident for follow-up is $400.

Prepared by: Peter M. Nakamura, MD, MPH KP
Phone: (907) 465-3090
Division: Public Health
Date/Time: 3/3/00 4:50 PM

Approved by Commissioner: Karen Perdue, Commissioner
Date: 3/6/00
Agency: Department of Health & Social Services

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COMMITTEE: Senate HESS

DATE: 3/8/00

Subject of meeting: SB 261 - Needle stick and Sharp Injury protections

SIGN-IN

PLEASE PRINT! NAME	ADDRESS (MAILING) & (ZIP)	PHONE	REPRESENTING	DO YOU WANT TO TESTIFY?
Bon Novotney	1120 Timberline CT 99801	7804300	Self	yes
Jake Mater	P.O. Box 490 Folsom PA 05763	1-16 353-1054	Aventis Pharma	Yes
Elmar Lindstrom	DHSS	465-1613		Yes
Lorraine L Dew	ASHNHA 426 Main St.	586-1790	ASHNHA	
Barbara Huff Tuckness	520 E 34	5654286	Teamsters	YES

COMMITTEE: **SENATE HESS**

DATE: MARCH 20, 2000

Subject of meeting:

SB 261-PROTECTION FROM NEEDLE & SHARPS INJURIES

SIGN-IN

PLEASE PRINT!

NAME	ADDRESS (MAILING) & (ZIP)	PHONE	REPRESENTING	DO YOU WANT TO TESTIFY?
Barbara Huff Tuckness	520 E 34th	561-8236	Teamsters	NO
Elmer Lindstrom	DHSS	465-1613	DHSS	X

AMENDMENT

OFFERED IN THE SENATE HEALTH, EDUCATION, AND SOCIAL SERVICES COMMITTEE

SPONSOR: Sen. Elton

TO: SB 261

Amend Section 1

After line 7, page 4, insert new subsection to read:

(g) Standards adopted under this section that exceed the requirements of bloodborne pathogens standard existing on the effective date of this section and standards adopted under subsection (b) of this section do not apply to the use of a drug or biologic, approved for commercial distribution or investigational use by the federal food and drug administration, that is prepackaged within administration system or that is used in a prefilled syringe. This subsection expires January 1, 2004.

Effect:
Manufacturers of pre-filled syringe devices are given three years after the effective date of the bill to comply with the requirements for engineered sharps injury protection in their devices.

Pharmaceutical Amendment.

February 28, 2000

Standards adopted under this section that exceed the requirements of bloodborne pathogens standard existing on the effective date of this section and standards adopted under subsection ( ) ( ) of this section do not apply to the use of a drug or biologic, approved for commercial distribution or investigational use by the federal food administration, that is prepackaged within administration system or that is used in a prefilled syringe.

Effect. The new standards adopted for bloodborne pathogens would not apply to certain drugs and biologics in prepackaged systems until approved by the federal drug administration

Aventis

Jacob I. Mater, II
State Regional Manager

Aventis Pharmaceuticals

Government Affairs
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Folsom, CA 95630
Tel. (916) 353 1054 / Fax(916) 353 1453
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The Honorable Mike Miller
Alaska State Senate
State Capitol
Juneau, AK 99801

March 6, 2000

Dear Senator Miller

As you are aware, a bill has been introduced in the Alaska State Legislature (S 261) which would require employers to adopt needlestick injury prevention programs for their healthcare workers.

Aventis Pharmaceuticals is in support of measures to improve the safety of healthcare workers against accidental needlesticks, but respectfully request that you consider a friendly amendment to ensure the safety of patients.

Aventis Pharmaceuticals manufactures Lovenox® (enoxaparin sodium injection), the world's leading low-molecular weight heparin, used primarily in the prevention and treatment of deep vein thrombosis, which can lead to pulmonary embolism, a potentially life-threatening condition.

Lovenox is available primarily in pre-filled syringes. These syringes do not include engineered sharps injury protection features. We are now working to modify this design and submit a newly-designed product to the federal Food and Drug Administration (FDA) for approval. This process is expected to be completed, at the earliest, within three years.

Based on our experience in California, which passed similar legislation in 1998, employers are likely to be confused as to their ability to use medications in pre-filled syringes which do not contain engineered sharps safety protections.

Because of the federal requirement that we gain FDA approval for a redesigned pre-filled syringe, we are not able to introduced a re-engineered system as soon as we would like.

Given this, we propose that the Alaska Senate Bill 261 be amended with the following language:

TRANSITIONAL PERIOD FOR CERTAIN DRUGS AND BIOLOGICS.-- THE USE OF A DRUG OR BIOLOGIC THAT IS PREPACKAGED WITH AN ADMINISTRATION SYSTEM OR USED IN A PREFILLED SYRINGE AND IS APPROVED FOR COMMERCIAL DISTRIBUTION OR INVESTIGATIONAL USE BY THE FEDERAL FOOD AND DRUG ADMINISTRATION SHALL BE EXEMPT FOR ANY STANDARD ADOPTED UNTIL SUCH TIME AS SUCH PRODUCT IS APPROVED FOR COMMERCIAL DISTRIBUTION BY THE FEDERAL FOOD AND DRUG ADMINISTRATION WITH INTEGRATED SHARPS INJURY PROTECTION FEATURES.

Several state legislatures are considering legislation to change their bloodborne pathogens standards. The states which have passed legislation which either exempts or delays implementation for standards affecting pre-filled syringes include Texas and New Jersey. Legislation including these provisions which have passed one house include Pennsylvania, Illinois, Ohio and Oklahoma. Other states are now considering bills which contain these provisions.

Finally, please understand that Aventis is moving ahead to introduce a new pre-filled syringe which contains these protections. We are supportive of efforts to ensure the safety of healthcare workers and are equally committed to assuring the continued availability of appropriate medications to patients.

Thank you for your interest. Please call if I can be of any assistance.

Sincerely,

Paul Baldwin
Director, State Government Affairs

SENATOR KIM ELTON

SB 261—Safer Needles Bill

Sponsor Statement

SB 261 brings needed protection to health care workers from accidental needlestick injuries.

Health care workers are at particular risk on the job because of the danger of disease transmission. Accidental needlesticks can transmit bloodborne diseases such as hepatitis B, hepatitis C, and human immunodeficiency virus (HIV). Nationwide, health care workers suffer between 600,000 and one million accidental needlesticks per year. Between 50,000 and 60,000 health workers have contracted serious diseases from needle sticks in the last decade, and on average one health care worker per week is exposed to HIV.[1] While HIV is the highest profile disease, experts now estimate that more health care workers will eventually die from exposure to hepatitis C than from HIV.[2] Medical workers are four times more likely than police officers to die from a job-related injury.[3]

A number of manufacturers currently produce safer needle devices with self-retracting needles, self-blunting tips, or other technology, and their effectiveness in reducing injuries has been demonstrated in evaluations by the Centers for Disease Control and Prevention. 250 such devices are FDA-approved, yet only 15% of hospitals use safer needles.[4]

Health care facilities have been slow to use safer needles because they are more expensive. But these devices save money in the long-term by reducing testing and care for workers accidentally exposed through needlesticks. The cost for testing following a high-risk needlestick injury is nearly $3,000, even when no infection occurs. A serious infection can cost upwards of $1 million when you include lost time and disability payments. In California, the first state to pass a safer needle law, hospitals and health care employers are expected to save $100 million per year thanks to reduced accidents. As ever more health care facilities use safer needles, prices can be expected to go down.[5]

SB 261 requires health care facilities to evaluate safer needle devices, and triggers new regulations requiring the use of safer needles when appropriate. The bill requires the Department of Labor to adopt regulations requiring health care facilities to:

- include safer needles as engineering and work practice controls (except in cases where a committee including frontline health care workers determines these devices will jeopardize safety);
- include a procedure for identifying safer needles in the facility's exposure control plan;
- update the exposure control plan as new technology is developed; and
- record exposure incidents in a sharps injury log.

---

[1] Source: *San Francisco Chronicle*, 4/13/98, p. A1
[2] Washington State Legislature, Senate Bill Report for ESSB 6416
[3] Source: *San Francisco Chronicle*, 4/13/98, p. A1
[4] Source: American Nurses Association
[5] Source: *San Francisco Chronicle*, 12/18/98

ALASKA SENATE
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SENATOR_KIM_ELTON@LEGIS.STATE.AK.US

In addition the Department of Labor may adopt regulations that include training and education requirements, measures to increase vaccinations, requirements for placement of sharps waste containers, and requirements for the use of personal protective equipment. The Department of Labor is required to compile a list of safer needle devices and to make the list available to employers. Finally, a needlestick injury fund is established which, subject to appropriation, may make grants for research, development, and product evaluation of safer needles.

Six states have already passed safer needle legislation and bills are pending in 20 states besides Alaska. In Washington, a similar bill recently passed the state senate by an overwhelming bipartisan margin. In Massachussetts, a safer needle bill was spurred on by testimony from the president of the Massachussetts Nurses Association, who acquired both HIV and hepatitis C from an accidental needlestick.

SB 261 is based on model legislation being used around the country. The American Nurses Association has led efforts to pass safer needle legislation at the state and federal level, and this bill is strongly supported by the Alaska Chapter of the ANA.

SB 261: Safer Needles Bill

Sectional Analysis

Section 1.

Creates new section: Article 13. Health Care Protections. Sec.18.60.880

Product Evaluations

Requires health care facilities to conduct product evaluations of needleless systems and sharps with engineered sharps injury protections that are used in the facility. The evaluation period must last at least six months and must be conducted by front-line health care workers representing all areas where the devices are used. The bill includes no deadline by which evaluations must be commenced or completed. The following categories of devices must be evaluated:

1. IV catheters
2. IV access devices (med ports, etc.)
3. Vacuum-tube blood collection devices
4. Blood-drawing devices including phlebotomy needle and tube holder, butterfly type devices, and syringes and other similar devices
5. Syringes used for purposes other than blood drawing
6. Suture needles
7. Scalpel devices
8. Any other category of device used at the employer's facility where there is a sharps injury risk

New Regulations Concerning Safer Needles

Requires the Department of Labor, by regulation, to adopt a standard concerning the use of needleless systems and sharps with engineered sharps injury protections for devices listed above. The regulations must say that:

- Needleless systems and sharps with engineered sharps injury protections must be included as engineering and work practice controls. This requirement is not applicable if an evaluation committee established by the employer determines by objective evaluation that use of the devices will jeopardize patient or employee safety. This can mean that the devices are not more effective at preventing accidental needlesticks or that the devices compromise patient care or safety. At least half of the members of the evaluation committee must be front-line health care workers.
- Each facility's written exposure control plan must include an effective procedure for identifying and selecting existing needleless systems and sharps with engineered sharps injury protections. The evaluation committee is responsible for identifying and selecting the devices. The evaluation committee is the same as that described for the six-month product evaluations: front-line health care workers representing all wards and medical specialities.
- The written exposure control plan must be updated to reflect progress in implementing use of safer needle devices, as determined by the evaluation committee. The updating must occur at least once every year.
- Information concerning exposure incidents shall be recorded in a sharps injury log.

Sharps Injury Log Requirements

Sharps injury logs must include at least the following information:

- Date and time of the exposure incident
- Type and brand of the sharp involved in the exposure incident
- Description of the exposure incident that must include:
    - Job classification of the exposed employee
    - The department or work area where the exposure took place
    - The procedure that the exposed employee was performing at the time of the incident
    - If the sharp had engineered sharps injury protections, whether the protective mechanism was activated, and whether the injury occurred before, during, or after activation of the mechanism
    - If the sharp had no engineered sharps injury protections, the injured employee's opinion as to whether and how such a mechanism could have prevented the injury, as well as the basis for the opinion
    - Whether an engineering, administrative, or work practice control could have prevented the injury, as well as the recorder's basis for the opinion

Regulations to Implement Section and Optional Additional Regulations

The Department of Labor shall adopt regs to implement the above, and to revise the bloodborne pathogen standard to prevent sharps injuries or exposure incidents. Regulations *may* also include:

- Training and education requirements
- Measures to increase vaccinations
- Requirements for the strategic placement of sharps containers as close to the work area as practical
- Requirements for the increased use of personal protective equipment

List of Available Safer Needles

The Department of Labor shall compile and maintain a list of existing needleless systems and sharps with engineered sharps injury protections, and shall make this list available to assist employers in complying with the above. The list may be developed from existing sources of information, including FDA, CDC, NIOSH, and US Dept. of Veterans Affairs.

Needlestick Injury Fund

Subject to appropriation, Department of Labor shall establish a needlestick injury fund. DoL can make grants from the fund for research into, development of, and product evaluation of, needleless systems and sharps with engineered sharps injury protections.

Definitions

Creates new section: Sec. 18.60.890 Definitions (pertaining to above)

Section 2

The above takes effect January 1, 2001

Questions and Answers
SB 261, the Safer Needles Bill

How many needlestick incidents occur in Alaska?
No state or national data on needlesticks is collected, so most studies reference the national estimate developed by the University of Virginia Health Care Worker Safety Center. That estimate is 600,000 to 1 million accidental needlesti[illegible]s per year. An estimate of Alaska needlesticks based on Alaska's percentage of the U.S. population in the 1990 census is: 1,327 to 2,211 per year.

Why are needlesticks so dangerous?
Needlesticks can transmit serious bloodborne diseases such as HIV, Hepatitis B, and Hepatitis C. The dangers of HIV are well known. Less well known are the dangers of Hepatitis C, a chronic disease affecting 4 million Americans which can have serious effects on the liver. Hepatitis C infection is the leading indication for liver transplantation; 5-7% of those infected with HCV will die as a result of their infection. There is currently no vaccine for HCV. Experts estimate that more healthcare workers will eventually die due to complications from occupational exposure to Hepatitis C than exposure to HIV. Hepatitis B is a chronic disease affecting 1.25 million Americans which can also result in complications to the liver. Vaccinations for HBV are available to health care workers and are believed to be 90% effective.

How frequently are serious diseases contracted through a needlestick?
Chance of Infection if Exposed to Blood Containing Virus
Hepatitis B: 6-30% (national estimate)
Hepatitis C: 5% (national estimate)
HIV: 0.03% (Alaska estimate)

In Alaska, using rough estimates of needlestick occurrence, disease prevalence, and Alaska's share of US population, this translates into yearly infection numbers of:
Hepatitis B: 1-3 workers infected
Hepatitis C: 1-2 workers infected
HIV: very low--less than 1 worker infected

What are the costs of infection?
According to the State of Maryland's recent Health Care Worker Safety Act Study Group Report and SEIU data from Washington State:

- $500 to $750 for standard testing following a needlestick
- $2,000 to $3,800 for testing and treatment following a high-risk needlestick injury
- $20,000 to $30,000 avg. annual drug costs for HIV treatment
- $20,000 to $30,000 avg. annual drug costs for HCV treatment (liver transplantation can raise cost of HCV infection to $500,000)
- Up to $1 million--The American Hospital Association estimate of costs to treat a health care worker with a serious bloodborne pathogen disease, including treatment, follow-up. lost-time wages, and disability payments

Using rough estimates for Alaska needlesticks and the costs of testing and treatment, the cost to Alaska health care facilities just for standard testing each year is roughly $663,500 to $1,658,250. This cost, of course, rises with high-risk needlesticks and treatment in cases of infection.

How much more do safer devices cost?
This depends on the device. Good examples are offered in the Maryland report:

Purpose of Device	Device	Unit Price (conventional)	Unit Price (safer)	Annual Cost for 250-300 Bed Hospital		
				Conventional	Safer	Incremental
Venous Blood Draw	Vacuum tube Phlebotomy Needle	$0.10	$0.33	$6,500	$22,000	$15,500
	Butterfly Needle	$0.65	$0.90	$11,000	$15,000	$4,000
IV Access	IV Catheter	$0.75	$1.75	$25,000	$58,500	$33,500
IM/SQ Injection/ Fluid Transfer	Hypodermic Needle/Syringe	$0.05	$0.25	$16,500	$83,500	$67,000

Is insurance affected by use of safer devices?
At least one major insurance provider, PHTS of South Carolina, has rewritten their underwriting requirements to require facilities covered by their workers compensation policy to have a "sharp object injury prevention program". The new policy is a preventive measure developed because PHT recognized the emerging threat of HCV and HIV infection from accidental needlesticks.

How effective are safer needle devices?
Again, this depends on the device. The CDC and others have conducted studies showing that safer needles can reduce needlestick injuries by up to 76%. Other studies show a zero rate of needlestick injuries when using the newest self-retracting syringes.

Surveys conducted by the Maryland study group show that nearly every facility responding indicated that there was a reduction in injuries after introduction of safer medical devices. No facility has discontinued use after implementation.

Devices with integrated safety features are significantly safer than standard devices. However, SB 261 allows health care facilities to determine this for themselves: if an evaluation committee, at least half of whose members are frontline health care workers, determines that a device jeopardizes patient care or worker safety, it need not be used.

How does this legislation differ from OSHA's November 1999 Compliance Directive on the bloodborne pathogen standard?
The November 1999 compliance directive was updated to clarify the intent of the bloodborne pathogen standard and to incorporate medical advances. The key revisions include:

- Annual Review of Exposure Control Plan: employers must ensure that their plans reflect consideration and use of commercially available safer medical devices
- Engineering Controls and Work Practices: emphasizes use of effective engineering controls
- Emphasizes that employers should rely on relevant evidence in addition to FDA approval to ensure effectiveness of devices
- CDC guidelines for post-exposure evaluation and follow-up for HIV and HCV
- Requires effective training whenever safer devices are implemented

State legislation complements and augments the message prescribed by OSHA. The SEIU, the American Nurses Association, and the State of Maryland Health Care Worker Safety Act Study Group Report detail reasons why the 1999 Directive is not adequate on its own to protect health care workers:

- Decisions about what constitutes safer devices can rest solely with the employer under the directive. Under this legislation, front-line health care workers are given a significant role in evaluating and selecting safer needles.
- The OSHA regulatory process is predominantly complaint-driven. Only a small fraction of facilities will be visited due to complaints by workers or for other reasons.
- The compliance directive is subject to court challenge because it provides detailed procedures for enforcement of the 1991 standard.
- The compliance directive is this Administration's interpretation of the bloodborne pathogen standard; it could change with successive Administrations
- The legislation provides for a much more detailed and product-specific sharps injury log than required by the directive.
- The Maryland study group concluded that the directive "may not be adequate in guaranteeing sufficient use of engineered sharps injury protection." They also agreed that "a clear, unambiguous revision of the bloodborne pathogen standard [through legislation] is warranted and necessary to ensure the widespread adoption and use of engineered sharps injury protection."

What information is currently collected on needlesticks?
Employers are required to complete an OSHA-200 log when an employee requires workers' comp due to an on-the-job injury. The Department of Labor's inspectors have access to these logs, as do employee organizations upon request. These logs do not require information on the type or brand of device involved in needlestick incidents, or other information about engineered sharps injury protection.

A note: It is estimated that 39% of all exposures go unreported.

Are safer devices available?
A wide variety are available, including syringes, IV catheters, safer blood-drawing devices, lancets, and scalpels. The US Patent Office has approved over 1,000 patents for safer needle designs and the US FDA has now approved for marketing 250 products with integrated safety features

What are other states doing about needle safety?
Legislation similar to the model legislation has passed in four states: California, Texas, New Jersey, Tennessee. Maryland passed a bill calling for a study group on health care worker safety. Hawaii passed a resolution calling for use of safer needles. Legislation is pending in 20 states besides Alaska.

Legislation which has passed varies from state to state. Legislation in "state plan OSHA states" covers all health care facilities and employees; Alaska, California, and Tennessee fall into this category. Legislation for other states covers only public employees since private employees are covered by federal OSHA; New Jersey and Texas fall into this category.

What if a facility is already using safer devices?
SB 261 reinforces the policies of facilities already using safer devices, requires the involvement of frontline health care workers in selecting and evaluating safer devices, and requires annual updating of exposure control plans to reflect advances in safer devices. The legislation complements and augments the Nov. 1999 OSHA Bloodborne Pathogens Compliance Directive, which already emphasizes the use and consideration of safer needle devices, and which facilities should already be addressing in their safety practices.

Where do needlesticks occur?

Patient rooms	34%
Operating rooms	23%
Emergency departments	7%
Intensive care units	7%
Out-patient offices	5%
Clinical laboratories	5%
Others	18%

**from EPInet data network, 1996*

Which workers suffer needlesticks and in what proportions?

Nurses	46%
Medical technicians	23%
Doctors	15%
Housekeeper/ laundry workers	5%
Other	12%

**from EPInet data network, 1996*

How many facilities already use safer needle devices?

Nationally only 15% of hospitals use safer devices. The data on Alaskan health care facilities is not available and would require a survey.

Does this legislation mean that Dept. of Labor will mandate which devices to use?

No. These choices are made by health care facilities and their employees through an initial six month evaluation period of safer devices, and subsequent evaluation as appropriate. Each facility can develop its own procedure for selecting devices, subject to the requirements of the bill. DoL will be required to maintain a list of safer needle devices to assist employers in complying with the bill.

Sources:

EPInet data network, see http://www.med.Virginia.EDU/medcntr/centers/epinet/
Service Employees International Union, see http://www.seiu.org/
American Nurses Association, see http://www.nursingworld.org/needlestick/nshome.htm#Legislation
State of Maryland Department of Health and Mental Hygiene Health Care Worker Safety Act Study Group, available at http://dhmh.state.mk.us/html/reprtk10.htm
San Francisco Chronicle "Deadly Needles" series, 4/13/98, 4/14/98, 4/15/98

Prepared by Senator Kim Elton's office

Alaska Hepatitis C Coalition

5350 Little Tree Street
Anchorage, AK 99507
(907) 563-7675

Senator Kim Elton
State Capitol Room 504
Juneau, AK 99801-1182

March 1, 2000

Dear Senator Elton:

The Alaska Hepatitis C Coalition supports the passage of Senate Bill 261"An Act relating to needle stick and sharps injury protections and the use of safe needles by health care facilities and health care professionals." We believe that this legislation will significantly reduce the risk of occupational exposure to blood borne pathogens via accidental needle sticks or percutaneous exposure through other sharp instruments in the health care setting.

The Centers for Disease Control and Prevention (CDC) states in the October 16, 1998 Morbidity and Mortality Weekly Report (MMWR) issue entitled *Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease*:

> Health care, emergency medical, and public safety workers should be educated regarding risk for and prevention of blood borne infections, including the need to be vaccinated against hepatitis B. Standard barrier precautions and engineering controls should be implemented to prevent exposure to blood. Protocols should be in place for reporting and follow-up of percutaneous or permucosal exposures to blood or body fluids that contain blood.

Senate Bill 261 will ensure that health care facilities provide a safer environment through careful product evaluation, enacting a formal exposure control plan and by implementing a sharps injury log.

It is conservatively estimated that 11,000 Alaskans are infected with HCV. It is not know how many of those individuals became exposed to the virus through accidental needle sticks while working in a health care facility, however several of our members believe that this was the source of their infection. Senate Bill 261 will provide additional protection to health care workers from becoming infected with the hepatitis C virus as well as other blood borne infections and we strongly encourage that it be passed into Alaska State Statue.

Sincerely,

Kendall Thomas, MS
President

TESTIMONY ON SB 261

I sustained a needle stick injury (my first), after 25 years of nursing, while working in the Emergency Department at Providence Alaska Medical Center. The "butterfly" device that I was using to draw blood did not have a safety sheathe. I recognize how important individual safety practices are in preventing any kind of injury, and most use these devices without problems, but the risk of life altering infections and diseases requires extra effort to protect those, who in a moment of rush or careiessness, might be exposed. My patient had Hepatitis C. I have been tested once and my test was negative, but the concern and stress until the final test at 6 months is negative has an impact on my husband and kids also.

The real cost to hospitals for using safety devices would be such a small fraction of the cost of giving safe, competent patient care. I do not know what expenses the hospital incurs when employees need follow-up testing and treatment, but I suspect the cost of just one incident of employee seroconversion would be greater by far than the added cost of safety devices.

Please support Senate Bill 261. Thank you.

Janice (Jay) Laxson, Registered Nurse
11901 Woodbourne Circle
Anchorage AK 99516-2554
907.345.3639

Subject: testimony re: needle sticks in nursing
Date: Tue, 07 Mar 2000 15:57:02 -0900
From: Wendy Alward <"markus@gci.net"@gci.net>
Reply-To: "markus@gci.net"@gci.net
To: Angie_Schmitz@iegis.state.ak.us
CC: polarmagic@webtv.net

Hello Angie,
I am an RN at Providence Alaska Medical Center and I would like to have my testimony included in the hearing tomorrow. I have been a nurse in an intensive care area for 9 years and have been stuck with contaminated needles, ie blood exposure at least 5 times, with numerous, 'near misses'. Most of these occurred when I was in a hurry due to staff shortages that resulted in high acuity assignments; Other times by coworkers.
I have been very fortunate in that I have not contracted HIV or any of the hepatitises thus far.
The fact that many other hospitals already have safe needless systems already in place confirms that this bill is very important.
What a relief it would be to be able to go to work and know that the risk of a serious exposure has been diminished substantially by having a needleless system in place.
Thank you for all of your time and effort in persuing this bill,
Sincerely, Wendy Alward RN BSN

Nursing Facts

From the American Nurses Association

Needlestick Injury

- Health care workers (HCWs) suffer between 600,000 and one million injuries from conventional needles and sharps annually. These exposures can lead to hepatitis B, hepatitis C and Human Immunodeficiency Virus (HIV), the virus that causes AIDS.
- At least 1,000 HCWs are estimated to contract serious infections annually from needlestick and sharps injuries.
- Registered nurses working at the bedside sustain an overwhelming majority of these exposures.
- Needlestick injuries are preventable. Over 80% of needlestick injuries could be prevented with the use of safer needle devices.
- Less than 15% of U.S. hospitals use safer needle devices and systems.
- In 1992, the Food and Drug Administration issued an alert to all health care facilities to utilize needleless IV systems wherever possible. This alert is merely a recommendation, not a mandate. Therefore, health care facilities are under no legal obligation to comply.
- The first safe needle designs were patented in the 1970s, and the FDA has approved over 250 devices for marketing as safety devices.
- More than 20 other infections can be transmitted through needlesticks, including: tuberculosis, syphilis, malaria and herpes.

Cost Savings from Needlestick Prevention

- Hospitals and health care employers in California are expected to save over $100 million per year after implementing the California Occupational Safety and Health Administration's requirement for safe needle devices.
- According to the American Hospital Association, one case of serious infection by bloodborne pathogens can soon add up to $1 million or more in expenditures for testing follow-up, lost time and disability payments.
- The cost of follow-up for a high-risk exposure is almost $3,000 per needlestick injury even when no infection occurs.
- Safe needle devices cost only 28 cents more than standard devices.

Hepatitis B

- Hepatitis B is now preventable due to the vaccine that must be offered to HCWs and is given to children at birth.
- Regulatory and legislative efforts were largely responsible for the reduction of deaths from hepatitis B as a result of vaccine programs.

- Following these regulatory and legislative efforts, including the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard, cases of hepatitis B in health care workers dropped from 17,000 annually to 400 annually–and continue to drop.
- Transmission rate: 2–40%

Hepatitis C

- Testing for hepatitis C after needlestick injuries was only recommended in 1998. It is a silent epidemic. There could be thousands and thousands of nurses with occupationally acquired hepatitis C who do not know it.
- Hepatitis C is the most frequent infection resulting from needlestick and sharps injuries. Of health care workers who become infected, 85% become chronic carriers.
- Chronic carriers have the potential to spread the disease to others, including their partners.
- Drugs that slow the progression of hepatitis C are available, but average $1,700 each month.
- Hepatitis C leads to liver failure, liver transplants and liver cancer. A liver transplant costs $500,000.
- At least 4 million Americans are infected with hepatitis C.
- Transmission rate: 2.7–10%

HIV

- Human Immunodeficiency Virus (HIV) is the virus that causes AIDS, a fatal disease.
- Advances in treatment prolong the time before HIV becomes AIDS. The drug treatment can cost up to $6,000 per month.
- 16,000 of the 600,000 to one million needlestick injuries each year result in HIV exposure.
- There are over 54 documented cases of HCWs with occupationally acquired HIV and at least 133 cases of possible transmissions of HIV.
- There are 35 new cases each year.
- Transmission rate: .2–.4%

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Return to the Reading Room.

Return to the Safe Needles Save Lives page.

COSTS AND SAVINGS ASSOCIATED WITH NEEDLESTICK INJURIES AND THE USE OF SAFER NEEDLE DEVICES

Costs for Treating Injured Health Care Workers

- $500 – cost for initial testing following a needlestick injury
- $2,200-$3,800 – initial cost for testing and treatment with prophylactic drugs for a health care worker injured by a potentially HIV-contaminated needle, but the illness not yet confirmed
- $20,000-$30,000 – average annual drug costs for a health care worker who develops HIV as a result of a needlestick injury
- Up to $1 million – The American Hospital Association estimate of costs to treat a health care worker with a serious bloodborne pathogen disease, including treatment, follow-up, lost-time wages, and disability payments
- $20,000-$30,000 - average annual drug costs to treat Hepatitis C
- $500,000 – potential lifetime treatment costs for someone with Hepatitis C

Workers Compensation and Liability Costs

- A study of insurance costs for needlestick injuries, reported that a single needlestick injury can cost up to $500,000 in workers' compensation costs
- A physician at Yale-New Haven Hospital in Connecticut was awarded $12.2 million by a jury for a needlestick injury that resulted in him acquiring HIV

Costs to a Health Facility for Safe Needles

- 7 cents – the cost for a conventional syringe
- 24 cents – the median increase in the cost for a safer needle device
- $70,000 – the additional cost to equip a 300-bed hospital for a year with safe blood collection, hypodermic, and IV catheter devices

Savings Associated with the Use of Safe Needles

- The California Occupational Safety and Health Standards Board estimated that the state will have a net saving of $106 million each year as a result of implementing the use of safe needles in all health care facilities. Although employers will spend $185 million for the new, safer technology and for expenses associated with increased record keeping, there will be savings of $291 million on the costs for diagnosing and treating needlestick injuries.

From: SEIU, Washington State

Department of Health and Mental Hygiene Health Care Worker Safety Act Study Group Report

Excerpts: members, exec. summary, + conclusions

Report to Georges C. Benjamin, MD

Secretary of DHMH

on

House Bill 287 (1999)

December 1999

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Upon the passage of any proposed legislation, it is clear that the regulatory process must be followed. The Annotated Code of Maryland, Labor and Employment Article authorizes the Commissioner of the Department of Labor, Licensing and Regulation (DLLR) upon recommendation from the Occupational Safety and Health Advisory Board to adopt regulations. The Advisory Board may propose or recommend reasonable regulations to prevent conditions that are detrimental to safety and health in each employment or place of employment in the State and that the Board finds are necessary to protect and to improve the safety and health of employees on the basis of circumstantial evidence and information. Proposed legislation would require the Board to advise, consult with, propose, and recommend to the Commissioner of Labor reasonable regulations specific to establishment of a Bloodborne Pathogen Standard governing occupational exposure to blood and other potentially infectious materials.

The Study Group recognizes that the process can be lengthy. For that reason, the Study Group encourages the designated agencies to pursue adoption of regulations with due diligence. Additionally, the Study Groups recommends that any proposed legislation and subsequently drafted regulations specifically provide reference to a time for implementation by employers of no more than twelve months after the final approval and the adoption of the proposed regulations.

7) Scope of the Regulation

There are particular procedures that employees perform that were identified as the primary functions that subject health care workers to injury:

1. Withdrawal of body fluids.
2. Accessing vein or artery.
3. Administration of medications or fluids.
4. Any other procedure with potential for a sharps injury exposure incident.

The Study Group agreed that the revised Bloodborne Pathogen Standard should specifically apply to protection of personshealthcare workers who are licensed, certified, or otherwise authorized in Maryland to provide health care services in the course of their activitiesemployment in the health care setting. These individuals are most at risk for sharps injuries in the normal course of their activities whether as an employeeemployment or as a volunteer healthcare provider. This designation thereby excludes medications administered within the home by care providers such as family members and those self-administering medications.

8) Other revisions as needed

Any additional revisions to the Bloodborne Pathogen Standards to prevent sharps injuries or exposure incidents should be based on continuing development of technology, prevention and treatment techniques.

Conclusion

It is evident that occupational exposure to Hepatitis B, Hepatitis C, and HIV are associated with workplace needlestick injuries and are a cause of significant morbidity for workers and expense for healthcare facilities. There continues to be a high incidence of sharps injuries in health care settings although engineered sharps injury protection devices are now available on the market for use in many procedures. The devices have been shown to help prevent needle-stick injuries, iIf used properly, these devices have been found to reducethe occupational exposure risks. Although there is a growth in the number of Maryland health care facilities that are using engineered sharps injury protection , for some procedures,

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Executive Summary

The Study Group on Health Care Worker Safety was convened by appointment of the Department of Health and Mental Hygiene (DHMH) Secretary, Georges C. Benjamin, in accordance with House Bill 287(1999). In consultation with stakeholders, Secretary Benjamin is required to submit a report to the Governor and to the General Assembly by January 1, 2000, on the establishment of a Bloodborne Pathogen Standard governing occupational exposure to blood and other potentially infectious materials.

Workplace needlestick injuries are associated with occupational exposure to Hepatitis B, Hepatitis C, and HIV and are a cause of morbidity and distress for workers and significant expense to the healthcare industry. The Study Group noted that the recent national response to address needlestick injuries has occurred in part because of the continuing high incidence of sharps injuries in health care settings. Engineered sharps injury protection (or saferty devices) have been developed to help prevent needlestick injuries. When, i used properly, these devices have been found to reduce the occupational exposure risk.

Key findings of the study group include:

- Although there is growth in the number of Maryland health care facilities that are using engineered sharps injury protection, 24% of facilities responding to the survey reported they did not use engineered sharps injury protection devices at all. Of the facilities utilizing engineered sharp protection, most are only using devices for intravenous therapy procedures.
- OSHA requirements for documentation of bloodborne pathogen exposure do not accurately reflect injuries caused by such exposures.
- Although the OSHA bloodborne pathogen standard includes language on the use of engineered sharps injury protection, it has not been an effective tool in promoting widespread use of engineered sharps injury protection .

The Study Group recommends the introduction of legislation amending the Bloodborne Pathogen Standard. The Study Group has provided draft legislation that includes key elements necessary to strengthen the standard. Such elements include a requirement for exposure control plans within facilities, procedures for identifying and selecting sharps prevention technology, a sharps injury log for recording all injuries, and training and vaccination protocols. Additionally, the group recognized that employers and the industry will need time to developadopt procedures and adopt technology, so reasonable time allowances should be made for implementation of new practices. Finally, due to recognized limitations in current sharps protection technology, four exceptions to the recommendations are proposed to ensure high standards of care for patient safety and comfort.

Introduction

The Study Group on Health Care Worker Safety was convened by Georges C. Benjamin M.D., Secretary of Health of the Department of Health and Mental Hygiene (DHMH) in accordance with House Bill 287(1999). House Bill 287 directed the Department of Health and Mental Hygiene to hold hearings and prepare a report on the establishment of a Bloodborne Pathogen Standard governing occupational exposure to blood and other potentially infectious materials. Secretary Benjamin is directed to submit a report on the results of the investigation and study, together with policy recommendations, to the Governor and to the

24% of facilities responding to the survey reported they did not use any engineered sharps injury protection devices. Although the Bloodborne Pathogen Standard includes language on the use of engineered sharps injury protection and has been revised to enhance enforcement efforts, it has not been an effective tool in promoting widespread use of engineered sharps injury protection. Therefore, the Study Group recommends the introduction of legislation amending the Bloodborne Pathogen Standard to better address healthcare worker safety in Maryland.

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OSHA National News Release

U.S. Department of Labor
Office of Public Affairs

National News Release
November 5, 1999
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Stresses employer use of new medical advances

OSHA REVISES BLOODBORNE PATHOGENS COMPLIANCE DIRECTIVE

A new directive issued today by the Occupational Safety and Health Administration will help minimize serious health risks faced by workers exposed to blood and other potentially infectious materials. Among the risks are human immunodeficiency virus (HIV), hepatitis B and hepatitis C.

The directive guides OSHA's compliance officers in enforcing the standard that covers occupational exposure to bloodborne pathogens and ensures consistent inspection procedures are followed. It updates an earlier directive issued in 1992 and reflects the availability of improved devices, better treatment following exposure and OSHA policy interpretations.

"We must do everything we can to protect workers who may be at risk of exposure to bloodborne diseases," said Secretary of Labor Alexis M. Herman. "This directive doesn't place new requirements on employers, but it does recognize and emphasize the advances made in medical technology. And it reminds employers that they must use readily-available technology in their safety and health programs."

The revised directive emphasizes the importance of an annual review of the employer's bloodborne pathogens program and the use of safer medical devices to help reduce needlesticks and other sharps injuries. OSHA does not advocate the use of one particular medical device over another. The directive also highlights basic work practices, personal protective equipment and administrative controls.

The emphasis on engineering controls results from OSHA's request last year for ideas and recommendations on ways to better protect workers from contaminated needles or other sharp objects.

"We received nearly 400 comments from health care facilities, workers and others," said OSHA Administrator Charles N. Jeffress. "They told us that safe medical devices already available are effective in controlling hazards and that wider use of such devices would reduce thousands of injuries each year."

The revised directive also includes detailed instructions to compliance officers on inspections of multi-employer worksites, such as home health services, employment agencies, personnel services, physicians and health care professionals in independent practices, and independent contractors.

Also included in the directive are decontamination requirements, guidelines on hepatitis vaccinations and post exposure treatments, and employee training.