

**STATE OF ALASKA
DEPARTMENT OF HEALTH &
SOCIAL SERVICES
CERTIFICATE OF NEED
NEGOTIATED REGULATIONS
COMMITTEE
REPORT**

Prepared by:

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Executive Summary

The Negotiated Rulemaking Committee meetings for the Certificate of Need (CON) held in October and November this year produced several strong recommendations based on high consensus of the group. They included;

- That the CON process as it is currently, is broken
- It should not be eliminated
- Clear definition and specificity on the Physician office exemption (POE)
- What should be in for CON and what should be out
- CON covered entities should be required to serve all comers regardless of their ability to pay
- CON should be in alignment with Medicare guidelines

Several other areas of consensus of the committee included;

- The need for an ad-hoc advisory group to support the state in reviewing equipment thresholds, new procedures and remodels/renovations related to CON
- The state would benefit from having an ad-hoc advisory group for technical expertise in disputed CON situations
- Recommendation that the state collect data that shows whether the CON process actually accomplishes its stated purpose of cost containment and access.
- The State be empowered to a higher level of enforcement and monitoring that providers are staying within their CON
- That for definition purposes Anchorage, Mat-Su, and Fairbanks would be considered large communities and all other areas in Alaska would be considered small communities.

Efficacy of the CON was a major discussion topic. Where the CON is designed to contain costs and improve access, the committee noted a lack of data on whether the CON process actually accomplishes its intended purpose. The committee acknowledged that any movement towards collecting data will be time consuming and that all providers of services should be included in data collection in order to get a more comprehensive picture. Concurrently, the committee also noted the need to protect smaller community hospitals in select areas from being driven out of business and that the CON process accomplishes that end. Failure to do so will leave the CON vulnerable to attack and elimination.

The Physician office exemption (POE) definition was the most discussed and contentious topic at every session. The committee debated throughout the

sessions the definition of what a physician office is and is not for purposes of exemption from the CON. While the committee did reach consensus on specific language for the POE, it was based on the fear of the misuses of the POE process as perceived by many members versus a more positive outcome driven definition.

The negotiated rulemaking committee has the distinct merits of bringing together stakeholders to derive consensus on issues that are of importance to their communities and the state. In this first attempt to reduce the litigious atmosphere surrounding the CON, there were two distinct stakeholders not represented on the committee;

1. Patient / consumer representation was absent from the committee. The absence of patient viewpoint would be valuable in future committees to ensure that the committee stays focused more on what is best for the citizens of Alaska rather than healthcare business interests.
2. State of Alaska Healthcare point of view and plan. Several times the lack of state and or community healthcare plans/ goals, vision was notably absent as needed information for the committee to use in making decisions. If a plan was developed the CON decisions could be made in reference to the community and state plans as a guide.

Finally, as a matter of improving the committee process it is recommended that once a committee member is selected that substitutions not be allowed as it interferes with the group dynamic and the ability of the group to reach consensus.

I. Introduction

KMD Services & Consulting was contracted by the State of Alaska, Department of Health and Human Services (DHSS) to facilitate the Certificate of Need Negotiated Rulemaking Committee. Kevin Dee was lead facilitator. This was the first ever attempt to bring various vested parties together to attempt to reach consensus on the "Certificate of Need" (CON) process, rules and regulations.

The Committee members were selected through a voluntary process by DHSS and five days of meetings to review and make recommendations were held. The committee was asked to look at anything and everything related to the CON process including statutes, regulations and processes. The dates of the meetings were; October 29-30, 2007, November 13-14, 2007 & November 20, 2007. There were between 19 – 21 committee members present at all meetings. Committee members were comprised of Doctors and Hospital administrators and one representative from DHSS . The actual participants of the committee varied from session to session due to substitutions. The committee members and their attendance are listed below.

Certificate of Need Negotiated Regulation Committee Members

Present at meeting = X , Absent = A, Substitute = Sub

	Represents	Name	10/29	10/30	11/13	11/14	11/20	Substitution
1	Imaging	Ward Hinger, Administrator Diagnostic Health of Anchorage	X	X	X	Sub	X	Aaron Woolrich
2	Imaging	Jeff Kinion, CEO Alaska Open Imaging Center Wasilla	X	X	X	X	X	
3	Imaging	Robert Bridges, MD Aurora Diagnostic Imaging, LLC, Fairbanks	X	X	X	X in am only pm = Sub	X	Kim Black sub in afternoon
4	Imaging	Chakri Inampudi, MD Alaska Radiology Associates Anchorage	X	X	X*	X	X	*Left prior to meeting end on 11/13
5	Imaging	Bradley K. Cruz, M.D. Alaska Imaging Associates, LLC, Anchorage	X	X	X	X	Sub	Lester Lewis, MD

	Represents	Name	10/29	10/30	11/13	11/14	11/20	Substitution
6	Hospital	Shawn Morrow, CEO Bartlett Regional Hospital Juneau	X	X	X	X	X	
7	Hospital	James Shill, CEO Northstar Behavioral Health Systems, Anchorage	X	X	X	A	X	
8	Hospital	Edward Lamb, CEO Alaska Regional Hospital Anchorage	Sub	Sub	A	A	Sub	Jordan Herget = 10/29 & 10/30 Paul Morris = 11/20
9	Hospital	E. Al Parrish, CEO/VP Providence Health System Anchorage	X in am only pm = Sub	X in am only pm = Sub	Sub	Sub	Sub	Joel Gilbertson 4/5 of sessions
10	Hospital	Mike Powers, CEO/Administrator Fairbanks Memorial Hosp./Denali Center Fairbanks	X	X	X	X	X	
11	Hospital	Norman Stephens, CEO Mat-Su Regional Medical Center, Palmer	X	X	Sub	Sub	X	Michael Zielaskiewkz
12	Hospital	Ryan K. Smith, CEO Central Peninsula Hospital Soldotna	X	X	Sub	Sub	X	Jason Paret
13	Physician group	Creed Mamikunian, M.D. Anchorage	X	X	X	X (am only)	Sub	Vicki Crumptoula
14	Physician group	Baxter Burton, CEO Alaska Heart Institute, LLC Anchorage	X	X	X	A	X	
15	Physician group	Gerald L. Nicholson, Administrator Katmai Oncology Group, LLC Anchorage	A	A	A	X	A	
16	Physician group	Jeremy Hayes Advanced Medical Centers of Alaska Anchorage	X	X	X	Sub in am / X pm	X	Cathy Giessel
17	Physician group	Bruce Jayne Alaska Surgery Center	X	X	X	X	Sub	William Pethick

	Represents	Name	10/29	10/30	11/13	11/14	11/20	Substitution
18	Association (physician)	J. Ross Tanner, ASMA President	Sub	Sub	A	A	Sub	ASMA E.D. James Jordan served as designated substitute
19	Tanana Chiefs	Victor Joseph, Health Director Tanana Chiefs Conference Health Svcs., Fairbanks	X	X	X	X*	X	*Left prior to meeting end
20	DHSS	Jay Butler, MD, FAAP, FACP Chief Medical Officer, DHSS Anchorage	X	X	X	X	X	
21	Association (hospital and nursing home)	Rod Betit, CEO Alaska State Hospital & Nursing Home Association	X	X	X	A	X	
22	Physician group	Mark Wade, MD. Fairbanks	NA	NA	X	X	A	Late entry to committee, Resigned after 11/14 meeting

II. Committee Negotiation Processes

A set of ground rules for discussion was implemented throughout the committee meetings;

ESTABLISHED GROUND RULES:

- ✚ Seek first to understand then to be understood
- ✚ Speak directly to your point
- ✚ Respect everyone's choices as right for them
- ✚ Spend 10% of your time identifying concerns & issues, 90% of your time identifying options & solutions
- ✚ Focus on choices and consequences versus right and wrong
- ✚ All Voices count
- ✚ Follow facilitator instructions

The committee used open group discussion to determine topics and points of view on each subject and questions for voting were developed. Voting was conducted using an electronic anonymous (Consensor) polling system to determine the level of consensus of the group on specific topics.

A working definition for consensus was developed by the group. 66% or greater was the determinant number to say that consensus was reached and the higher the percentage the greater the level of group consensus. A show of hands established 70% or higher for high consensus

Discussion topics

The Committee generated a set of agenda topics for discussion framed around the purposes of;

- Clarifying the CON definitions and processes
- Reducing litigation
- Assisting in cost containment
- Assisting in access
- leveling the playing field

Primary topics for discussion included;

- ✓ Elimination or modification of CON
- ✓ Thresholds
- ✓ Definitions
- ✓ Timely processes – Application, review, determination , appeal
- ✓ Enforcement of CON
- ✓ Physician Office Exemption
- ✓ Radiology
- ✓ Ambulatory Surgery centers

The specific discussions and subtopics of discussion are listed in the notes (attached) and were initially global (example: Eliminate the CON?) and then became more specific as decisions and consensus were reached on each item (example: percentage of radiology reports interpreted locally to qualify for Physician office exemption (POE)).

The committee moved through the topics and strong consensus and recommendations were reached in many areas. Other votes when diametrically opposed parties were unable to reach a common ground reflect areas of compromise.

Recommendations for future rulemaking negotiations and process

Several committee members noted the absence of patient and community representation. This was most adamantly put forth by Dr. Wade in his comments and committee evaluation. Dr. Wade commented that the committee was highly self interested in the financial impacts of the CON to their worlds and “protecting their own turf” versus interest and investment in what is best for patients for communities. The absence of Patient advocacy or a State of

Alaska, Healthcare plan, meant the only voices heard were from the financially vested physicians and hospitals. Though several hospitals represented were community hospitals, there were few comments about what was best for patient, access or cost containment. Most comments were concerning what was best for those present. Diversity of representation must be present in order to ensure a balanced approach to this volatile topic.

Substitutions for committee members were allowed due to the short notice of the scheduling of the committee meetings and as a method to maintain representation. This had a negative effect on the building of consensus. Consensus building is best served when a group gets to know each other's interests and concerns over time. This allows for trust and common interest to be developed. The allowance of substitutions goes a long way in isolating positions and interests.

The absence of data for the efficacy of the CON was duly noted by committee members and the need for it was also highly recommended. The lack of overall reference points including data diminished the ability of the group to have a more substantive process and eliminate the personal interest factors from the room. The development of cohesive plans by communities and the State of Alaska regarding healthcare services will go a long way in guiding the CON process in ensuring the needs of a community are met. The ongoing collection and analysis of utilization and capacity data would go a long way in reducing disputes and making CON decisions more defensible.

III. Areas of High Consensus

HIGH CONSENSUS REACHED FOR THE FOLLOWING*:

- Eliminate CON fully? 88.89% NO.
- Radiation therapy to be subject to CON? 89.47% YES.
- Imaging services subject to CON? 83.33% YES.

- Should a new committee member be added? 70% YES.
(The member was not added originally due to a communication issue).
- Should ambulatory surgery be included in CON? 85% YES.
- That statutorily defined Health Care Facilities, by definition, do not include physician offices. 100% agreed
- P.O.E. should be discussed separately from Radiology proposal.
84.21%, YES
- Should CON programs require all entities to serve all patients?
78.95%, YES
- Should CON processes and definitions be in alignment with Medicare
80%, YES
- Should Ad-hoc advisory groups be formed to assist DHSS in technical or contested decisions, what type? 73.68%, YES
- Recommend the state to seek out resources for clarification of issues in CON – tech advisory 94.74%, YES
- All facilities/equipment above the threshold must request P.O.E. letter of exemption - State issues letter of determination, 71.43%, YES
- The decisions reached are the best we can do, 71.43%, YES

**Please refer to "Consensor results" attachments for raw results*

IV. Areas of General Consensus

General Consensus was defined as either general agreement by show of hands, verbal support of the group to a concrete concept without opposition, or a vote that achieved between 66% and 71% (see attached meeting notes and "Consensor results" for raw voting results).

Different definitions for smaller communities needed for the CON process.

There are no hard deadlines in the CON process. Committee recommends the state establish process timeline deadline lengths, in days.

Committee asked who can file an appeal? *Reference: Current regulations; must prove you are truly adversely affected party in order to file an appeal. If you don't prove you're adversely affected there may be a consequence. Committee decided that the burden is on the appellant.

Who has the authority to enforce? The Commissioner should have the authority.

Committee requests that the state clarify: Appellants should have to prove they're providing "similar" services (make less vague). Recommendation to state: clarify what is "similar"

- Laws should be passed requiring physician's offices – or those practicing medicine have to serve all comers (all patients regardless of whether they have insurance or are able to pay).
- The CON Committee agreed by show of hands that "quality" was off the table for discussion as related to the CON. The Committee agreed that quality assurance is important, but better addressed in other forums.
- All committee members agreed that they wanted to protect smaller communities and let larger communities have competition.

- Leave Financial thresholds as currently defined and request clarification on items below, as noted:

Equipment Thresholds:

Recommendation: state needs to clarify definition of equipment – differentiate between facility equipment and medical equipment (#2 on page 18) via an advisory group (see below):

Advisory group	<p>Clearly define the differences between which items require CON</p> <ul style="list-style-type: none"> • Refurbished equipment • Novel scope of services (possible CON) • Replacement equipment <ul style="list-style-type: none"> a. Same purpose b. New equipment
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Facilities Thresholds:

Recommendation: state needs to clarify definition of facilities

Advisory group	<p>Clearly define the differences between which items require CON</p> <ul style="list-style-type: none"> • Refurbished, remodeling existing facilities, renovating and/or repairing existing facilities for same use, same scope of services– no added services • Novel scope of services • Replacement facilities <ul style="list-style-type: none"> a. Same purpose b. New facilities
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- State needs to fund a data driven process in order to avoid a litigious CON environment.
- Ambulatory Surgery Centers need to be defined in State Statutes or Regulations.

- Increase Consistency in processes and timelines to eliminate loopholes.
- Level the playing field and create consistency in the POE application process. Everyone wants to level the playing field. Make the process crystal clear with rules for the Commissioner to follow.
- Ambulatory Surgery Centers require CON process
- Ultrasound Services are not included in CON
- All facilities and equipment above the threshold must request for POE letter of exemption

V. Areas of Non-Consensus

Definitions for the Physician Office Exemption (POE) were the most controversial topic throughout all the sessions. The POE was by far the biggest issue for the group and was repeatedly discussed in varying formats. The committee revisited this area in varying approaches with evolving dialog at each turn. This was reflected in the progression of numerous votes that did not reach consensus on the POE exemption definitions below. **However, the committee eventually reached consensus on the final vote for the POE during the last session (See IV. Physician Office Exemption below).**

The following represents the areas that were discussed in parsing the disputed topics of POE and radiology definition for POE. The lack of any consensus in these questions shows the diametrically opposed positions and interests that have led to the current spate of litigation.

Two additional areas of topical discussion included:

- 1) Expansion of imaging services in the state by entities other than hospitals
- 2) Development of free standing ambulatory surgery centers. (eventually reached high consensus that Ambulatory Surgery centers to be included in the CON)

While discussed separately, both issues had common points.

Some committee members did not want physician groups opening surgery centers "to treat their own patients" but were content to let any individual physician groups acquire any imaging equipment, to treat "their own patients".

Imaging specialists seemed very concerned about the unfettered expansion of imaging equipment by physicians who, until recently, never directly used or owned this equipment, were unfamiliar and untrained in the equipments appropriate and safe utilization.

The committee voted during the first session (October 29-30, 2007) on how to handle the physician office exemption issue and ranked them in the following order:

- Mitigate – 24.7%
- Accommodate – 20.8%
- Transfer – 19.5%

- Eliminate – 18.2%
- Avoid – 16.9%

No Consensus was reached in determining how to approach the POE issue.

Initially, No Consensus was reached initially in determining whether other partners besides hospitals be allowed for POE exemptions. Vote was split 50-50.

Initially, No Consensus was reached on whether other partners besides hospitals be allowed for P.O. exemptions. Vote was split 45% yes against 55% no. (this was re-voted on again later)

No Consensus was reached on whether physician ownership should be 100% for P.O. exemption from the CON process. 35% yes, 65% no (this was voted on again later with high consensus).

The group tried again to determine what percentage of ownership should physician's have for a P.O.E. (physician's office exemption). This time the committee was given 5 choices and results were split as listed below:

- At least 40% - 8 votes
- Greater than 50% - 4 votes
- 65% - 2 votes
- 75% - 4 votes
- 85% - 2 votes

No Consensus was reached on whether anyone can be a minority partner in a physician's office. Vote was split 52.63% vs. 47.37%.

No Consensus was reached when the committee tried to rank (in order from highest to lowest) the percentage for physician owned, when given the following choices, with results below:

- Physician owned 100% - 6 votes
- Physician owned with a hospital – 8 votes
- Physician with anyone – 6 votes

No Consensus was reached when the physician owned percentage question was changed to allow only 2 choices:

- Physician owned 100% - 13 votes
- Physician with anyone – 7 votes

No Consensus was reached for E&M Physician (non radiologist) 100% Physician owned. Vote was split 60% yes, 40% no.

No Consensus was reached for Radiologist – majority ownership with anyone. Split vote: 60% yes, 40% no.

No Consensus was reached when asked to: discuss small and large communities together. Split vote with 57.89% yes and 42.11% no.

No Consensus was reached: Discuss E&M and Radiology separately? Split vote: 52.63% yes and 47.37% no.

No Consensus was reached on the following question:

Physician ownership E&M and Radiologists – large communities:

75% - 8 votes (=38.10%)

100% - 13 votes (=61.90 %)

No Consensus was reached for:

POE – large communities: Split vote with 100% physician owned – 60% and partner with anyone 40%.

No Consensus was reached for non-radiologists – large communities: 100% owned received 57.89% of the votes and partner with anyone received 42.11% of votes.

VI. Physician Office Exemption: Final Consensus

Despite the opposing positions of many of the committee members in approaching the POE issue there was a general consensus that the exemption was a loophole as written and needed to be amended in order to protect interests. The committee wrestled the most with who could own a physician's office. The group also asked who shouldn't be a partner? They agreed that publicly traded companies cannot be a physician's office partner. A turning point on the last day was when one committee member described how the POE had worked against their hospital and that if it could happen to them it could also happen to anyone. After protracted discussion and reversing itself on ownership percentages the committee reached consensus that in order to qualify for the POE the physician office must be 100% owned by physicians (71.43%, YES). A higher degree of consensus would have been obtainable if those committee members with a vested financial interest in the vote were exempted from voting.

A high consensus was obtained for recommending the definitions for qualifying for the POE (derived from medicare guidelines) and amended by the committee, be as follows;

INDEPENDENT DIAGNOSTIC TESTING FACILITIES (IDTFs)

All suppliers that perform diagnostic tests, other than clinical laboratory or pathology tests, and are required to enroll as an IDTF. Not all suppliers that perform diagnostic tests are required to enroll as an IDTF. Generally, an entity can bill for the technical component of the diagnostic tests without an IDTF enrollment if it has the following characteristics:

- A physician practice that is owned 100%;
- A facility that primarily bills for physician services (e.g., evaluation and management (E&M codes) and not for diagnostic tests;
- A facility that furnished diagnostic tests primarily to patients whose medical conditions are being treated or managed on an ongoing basis by one or more physicians in the practice;
- The diagnostic tests are performed and interpreted at the same location where the practice physicians also treat patients for their medical conditions.

However, if a substantial portion of the facility's business involves the performance of diagnostic tests, the diagnostic testing services may be sufficiently separate business to require enrollment as an IDTF. In that case, the physician or physician group practice can continue to be enrolled as a physician or physician group practice but are also required to enroll as an IDTF.

Diagnostic Radiology – Many diagnostic tests are radiological procedures that require the professional services of a radiologist. We recognize that a radiologist's practice is generally different from those of other physicians because radiologists usually do not bill E&M codes or treat a patient's medical condition on an ongoing basis. A radiologist or group practice of radiologists is not necessarily required to enroll as an IDTF. A radiologist or group of radiologists, are not required to enroll as an IDTF if all of the following conditions are met:

- The practice is owned 100% by radiologists, Physicians whose primary practice is Diagnostic Imaging and occasionally perform evaluation;

- The owning radiologist(s) and any employed or contracted radiologist(s) regularly perform physician services (e.g., test interpretations) at the location where the diagnostic tests are performed (>70% of tests);
- The facility does not usually purchase interpretations (generally interpreted <30% of tests);
- The billing patterns of the enrolled facility indicate that the facility is not primarily a testing facility and that it was organized to provide the professional services of radiologists (e.g., (1) the enrolled facility should not be billing for a significant number of purchased interpretations, (2) the facility should rarely bill for the technical component of a diagnostic test, (3) the facility should bill for substantial percentage (at least 70%) of all interpretations of the diagnostic tests performed by the practice), and
- The facility ordinarily bills globally

VII. Other Committee Recommendations

The following recommendations are a combination of general committee member comments and submitted recommendations by committee members

The Alaska State Medical Association (ASMA), in a letter dated November 6, 2007 to Karleen Jackson and Kevin Henderson, the House of Delegates (ASMA's policy making body) states that they support and advocate for the elimination of the entire CON program, except in small communities in Alaska. The reason they support the program only in small communities is because "Apparently, the State is not collecting nor analyzing sufficient data to show that the CON program has met its objectives."

The committee requests the state to define "excessive" and "need" more clearly in the regulations.

Community populations should be counted and need should be determined consistently (i.e.; count military/Native consistently the same). The population formula should be subject to revalidation if/when the population changes.

The committee would also like to see a state health plan/vision developed.

CON Process:

- Standards should be used as decision criteria
- Should be a data driven process
- A letter should be sent to CON P.O.E. grantees requiring them to submit data (# of patients served, etc.)
- Needs should be based on data, according to community (need community plans)
- Take market forces into consideration: can hospitals compete in the geographic area?
- Consider the capacity of each community
- CON grantees should be subject to revalidation based on data/numbers/need and changes
- The CON process should specify a window of response for other (competing) CON applications.

Administrative Hearing Process Recommendations:

- Needs to be more timely (90 days) *Note: Lawsuits start after the state decision or if it is taking too long.*

To curb lawsuits;

1. **Provide clear definitions** of the following:
 - Physician offices (see recommended language);
 - Define a small community? (Population) Population and capacity need to be looked at, in regard to the process.
2. **Get and Provide accurate data**, The State needs to provide better data and statistics according to geographical area (from discussion specific to definition of POE in CON process)
3. **Make administrative processes more timely**
4. **Create a consistent review process**

VIII. Attachments

Notes from sessions

Raw Consensor data in excel format

Session 1: October 29, 2007

ESTABLISHED GROUND RULES (which also apply to the rest of the committee meetings):

- Seek first to understand then to be understood
- Speak directly to your point
- Respect everyone's choices as right for them
- Spend 10% of your time identifying concerns & issues, 90% of your time identifying options & solutions
- Focus on choices and consequences versus right and wrong
- All Voices count
- Follow facilitator instructions

Decision Considerations:

Quality & Safety

Cost

Access

Utilization

Purpose(s)

Public Duty

Level playing field

HOPES

Something we can all work with
Bring historical perspective current
From litigation to cooperation
Find common ground
Recognizing behavioral health needs
Balanced
Clarity/working agreements
Access
Unique markets:
geographic/demographic
Fairness: patients/providers
Alignment to demographic similar states
Reduce litigation
Level playing field
Quality, access, safety

CONCERNS

Certificate process not working
Current uncertainty/frequency of changes
Complexity
Diversity of interests
Anti-competitive
Competitive vs. non-competitive
Barriers

Preliminary Topics of Interest (that were brought up-for open space breakout groups)

Statutes

Scope

CON vs. No CON - Elimination of CON

What is competition in medical field?

What is CON accomplishing?

Purpose of CON?
Public duty of health care providers
Regulations
Quality: affected by what? Measured how? What is quality?
Cost: effective at controlling cost?
Definition of Cost: cost/charge (per unit? Global? By utilization?)
Applying for CON

OPEN SPACE BREAKOUT TOPICS (actual process):

~~Eliminate CON fully~~ (CONSENSUS not to eliminate CON fully)
~~Keep it as is~~ (CONSENSUS that CON cannot stay as is)
Modify CON substantially (more robust/add/clarify)
Eliminate CON mostly (change scope to regulate only a few fields)

RESULTS OF OPEN SPACE BREAKOUT GROUPS

ELIMINATE FULLY:

Revise first then decide if want to eliminate
Eliminating CON eliminates contributions to non contributing services
High margin vs. low margin
Mid size markets hurt even more (selective – high payor services)
Would aid in selective high payors recruitment / retention
Doesn't aid in recruitment / retention
A fair and transparent process
AK: Some of highest healthcare costs in nation (system broke)
Unfettered free market (does not exit, can be destructive)
Hospitals not free to compete
Population dependent
Strains on human resources
Creates open competition
Private sector serves public duty 2%-10%
Will bleed away from hospitals, could cause raised prices
Any willing provider
Payors can contaminate free market
Jeopardize public trust to provide emergency and charity care proportionate to the community
CON does not contain costs

MODIFY SUBSTANTIALLY

Adequate resource and staff to service appropriately
Accurate need assessments (utilization, tracking, capacity calculation)
Populations (Native, military)
Less onerous Process (application)
Define quality
Credentials

Clarification (IDTF, physician office, dollar threshold, CHS definitions vs. state definition, service, affected vs. non-affected parties)

Modification procedure

Review of new services and community(s)

ELIMINATE MOSTLY:

What vs. Who (What is services, ie MRI. Who is physician office, hospital and is a location)

Why – hospital vs. independent?

Physician rep comment: eliminate all but small geographic

Eliminate all except for psychiatric

Who's here? (representing field)

To do so would negatively impact full-service hospital's ability to provide care such as Emergency and charity care, proportionate to community size, but not as much so as "fully" eliminating CON

Geographic

Maintain psych, nursing homes, outpatient diagnostic – further define, surgery center, beds

ASCs – shouldn't require CON

Based on population size?

Increase threshold for requiring CON

What's In (for future discussions)

Health Care Facilities (tab 4, page 9) - CONSENSUS

- Private, municipal, state or federal hospital
- Psychiatric hospital
- Independent diagnostic testing facility
- Residential Psychiatric Treatment Center
- Tuberculosis hospital
- Skilled nursing facility
- Kidney disease treatment center
- Ambulatory Surgery Center

Radiation Therapy

Imaging

- PET
- MRI
- CT
- Mammography
- Nuclear Medicine
- Cath Labs

New Services

IDTF vs. Physician's Office

Thresholds

Session 1: Day 2 : October 30, 2007

The CON Committee agreed that quality was off the table for discussion.

Recommendations to the state:

The committee would like to ask the state to define "excessive" and "need" more clearly.

The committee would also like to view a state health plan/vision.

"Intermediate Care Facility": The committee decided to revisit this issue when the group discusses PROCESS in future meeting(s).

"Who" Discussion:

- Physicians
- Anyone who wants to provide a what
- Whose money is it?
- Type of organization
- Owner structure (who are they? How are they integrated?)

The following was agreed upon by the committee at the end of the October 30, 2007 meeting by a show of hands:

What physician offices would be exempt?

- Not a facility
- Independent from hospital (financially & managerially)
- Appropriately licensed and certified
- Works within scope of practice

Radiation Therapy Discussion:

What would radiation therapy (out of a hospital) in a physician's office look like?
(e.g., radiotherapy seed business)

- Independent of hospitals
- Work within scope of practice
- Multiple equipment types
- Majority ownership by physician or physician hospital
- Licensed by NRC or state certified
- Local presence by owners

*note: hospital ownership of radiology equipment was tabled to the next meeting

A show of hands at the end of the second day of the meeting determined the start for radiology definition would be:

Paragraphs one and two of the CMS handout and then add the second paragraph of Chakri's definition.

(the following two paragraphs are excerpts from Attachment 2 on page 55 of CMS 855B (11/2001) and the last section was added by the CON Negotiated Regulation Committee on 10/30/07)

INDEPENDENT DIAGNOSTIC TESTING FACILITIES (IDTFs)

All suppliers that perform diagnostic tests, other than clinical laboratory or pathology tests, and are required to enroll as an IDTF must complete this attachment. CMS requires the information in this attachment to determine whether the enrolling supplier meets all IDTF standards. Not all suppliers that perform diagnostic tests are required to enroll as an IDTF. Generally, an entity can bill for the technical component of the diagnostic tests without an IDTF enrollment if it has the following characteristics:

- A physician practice that is owned, directly or indirectly, by one or more physicians or by a hospital;
- A facility that primarily bills for physician services (e.g., evaluation and management (E&M codes)) and not for diagnostic tests;
- A facility that furnished diagnostic tests primarily to patients who medical conditions are being treated or managed on an ongoing basis by one or more physicians in the practice;
- The diagnostic tests are performed and interpreted at the same location where the practice physicians also treat patients for their medical conditions.

Diagnostic Radiology – Many diagnostic tests are radiological procedures that require the professional services of a radiologist. We recognize that a radiologist's practice is generally different from those of other physicians because radiologists usually do not bill E&M codes or treat a patient's medical condition on an ongoing basis. A radiologist or group practice of radiologists is not necessarily required to enroll as an IDTF. A radiologist or group of radiologists, are not required to enroll as an IDTF if all of the following conditions are met:

- The practice is owned by radiologists, a hospital, or both;
- The owning radiologist(s) and any employed or contracted radiologist(s) regularly perform physician services (e.g., test interpretations) at the location where the diagnostic tests are performed;
- The billing patterns of the enrolled facility indicate that the facility is not primarily a testing facility and that it was organized to provide the professional services of radiologists (e.g., (1) the enrolled facility should not be billing for a significant number of purchased interpretations, (2) the facility should rarely bill for the technical component of a diagnostic test, (3) the facility

should bill for substantial percentage of all interpretations of the diagnostic tests performed by the practice), and

- A substantial majority of the radiological interpretations are performed at the practice location where the diagnostic tests are performed.

Paragraph to be added to CMS (recommended by CON Committee on 10/30/07):

Physicians whose primary practice is Diagnostic Imaging and occasionally perform evaluation

- The facility is owned by physicians, a hospital or both;
- Test interpretations are usually performed at the location where the diagnostic tests are performed (>70% of tests);
- The facility does not usually purchase interpretations (generally interpreted <30% of tests);
- The facility ordinarily bills globally

Sheraton Hotel, Josephine's Gallery
Session 2: November 13 & 14, 2007

Committee Members Present November 13, 2007:

- | | |
|------------------------------|-----------------------|
| 1. Mark Wade | 11. Jeff Kinion |
| 2. Robert Bridges | 12. Brad Cruz |
| 3. Ward Hinger | 13. Joel Gilbertson |
| 4. Jeremy Hayes | 14. Bruce Jayne |
| 5. Victor Joseph | 15. James Shill |
| 6. Shawn Morrow | 16. Creed Marnikunian |
| 7. Rod Betit | 17. Jay Butler |
| 8. Michael Zielaskiewkz | 18. Jason Paret |
| 9. Paul Morris (for Ed Lamb) | 19. Baxter Burton |
| 10. Mike Powers | |

ESTABLISHED GROUND RULES (applies to all committee meetings):

- Seek first to understand then to be understood
- Speak directly to your point
- Respect everyone's choices as right for them
- Spend 10% of your time identifying concerns & issues, 90% of your time identifying options & solutions
- Focus on choices and consequences versus right and wrong
- All Voices count
- Follow facilitator instructions

Decision Considerations:

Will it reduce litigation?

Will it assist in cost containment?

Will it assist in access?

Does it level the playing field?

HOPES

Discuss Ambulatory Surgery Centers

CONCERNS

CON ends up in court and judges end up making decisions: to date committee has not discussed

NOTES FROM CON SESSION 2: *November 13, 2007*

Clarification requested regarding Tribal Clinics and how CON may affect them.

- State should be aligned with federal in regard to Tribal facilities
- Need clarity or specific language regarding Tribal Facilities included in CON for planning purposes

AGENDA ITEMS TO DISCUSS

(consensus prioritization – voted on with results of prioritization below)

1. P.O. Exemption (22%)
2. Thresholds (19%) -
3. Process tied with Enforcement of CON (16% each)
4. Ambulatory Surgery Centers (14%)
5. Tribal Clinics (13%)

RADIOLOGY / P.O. EXEMPTION

P.O. Exemption

- ✓ Financial Interest / Actively Participating
- ✓ Directed by Owner Physicians
- Should hospital ownership be allowed for P.O. Exemption?
- What does majority owned mean? (>70% - consensus)
- Other than hospital investors allowed?

What should a P.O. (non-physician) partner look like (for POEs)?

- Anyone
- No authority on day to day
- Non-medical, then expertise in area involved – skill of expertise
- Active in the field of practice
- Vested interest in healthcare of community

Who shouldn't be a partner?

- Publicly traded companies

APPEND

- As stated, CMS test (still to be decided on bullet one).

Bullet one: A physician practice that is owned, directly or indirectly, by one or more physicians or by a hospital; (still TBD)

From 10/29 and 10/30/07 notes on pages 6 & 7:

- Recommendation to clarify language on bullet 3 of diagnostic radiology office
- Recommendation to clarify bullet 4 of E&M
- Still TBD on bullet 1 (of IDTF) - ownership

Committee recommends adopting as stated in CMS test from notes pages 6 & 7 (as appended).

Committee noted that definitions don't match up with CMS.

Physician's Office Exemption (doctor involved must have):

- Financial interest
- Majority ownership
- Skin in the game ("actively practicing" physician
- Could be hospital or others

Why should hospitals be the only entity allowed to partner with physicians offices? At what point is it about community and what point is it about profit?

NOTES FROM CON SESSION 2: *November 14, 2007*

MORNING

Committee Members Present November 14, 2007:

- | | |
|---------------------------------------|------------------------------------|
| 1. Victor Joseph | 11. Creed Marnikunian |
| 2. Bruce Jayne | 12. Brad Cruz |
| 3. Aaron Wollrich (for Wade Hinger) | 13. Jeff Kinion |
| 4. Robert Bridges (Kim Black in pm) | 14. Chakri |
| 5. Cathy Giessel (Jeremy Hayes in pm) | 15. Joel Gilbertson |
| 6. Michael Zielaskiewicz | *14 people voting during afternoon |
| 7. Gerald Nicholson | |
| 8. Shawn Morrow | |
| 9. Mike Powers | |
| 10. Jason Paret | |

CON Process

- Advisory Committee: Panel of impartial knowledgeable individuals (specific to issue at hand)
- Local knowledge to get true determination of need

RECOMMENDATIONS TO STATE:

Standards should be used as CON decision criteria, in a data driven process that takes community plans and market forces into account, with a letter requiring P.O.E. grantees to submit data to the state

CON Process:

Standards should be used as decision criteria

- Should be a data driven process
- A letter should be sent to CON P.O.E. grantees requiring them to submit data (# of patients served, etc.)
- Needs should be based on data, according to community (need community plans)
- Take market forces into consideration: can hospitals compete in the geographic area?
- Consider the capacity of each community (grantees subject to revalidation based on data/numbers/need)
- Should the CON process specify a window of response for other (competing) CON applications?

Administrative Hearing Process Recommendations:

Needs to be more timely (90 days)
Who can contest decision? *Note: Lawsuits start after the state decision.*

To curb lawsuits

Recommend to state:

- 2) Provide clear definitions of the following:

- Physician offices,
 - Define a small community? (Population) Population and capacity need to be looked at, in regard to the process.
- 3) Get and Provide accurate data
 - 4) Make administrative process more timely
 - 5) Create a consistent review process

Needed from the state prior to November 20, 2007 (the next CON committee meeting):

- Need data from state – go back 2 years and group appeals according to the nature of appeals. (need data by 11/20/07)

Enforcement Discussion took place and items were voted on regarding enforcement.

AFTERNOON DISCUSSION NOTES (11/14/07 PM):

(Discussion specific to definition of P.O.E. in CON process)

State needs to provide better data statistics according to geographical area.

Different definitions for smaller communities needed for the CON process.

Small P.O.E.

100% physician owned

Partner with local hospitals

Partner with anyone in community (dividend)

What is the definition of a small community? What about the Kenai Peninsula?

Would there be a different advisory committee for each specific situation? That would be too big of a burden on the state.

Large communities:

Anchorage, Mat-Su, Fairbanks: all others are small communities.

*Populations should be counted and need should be determined consistently (military/Native).

The population formula should be subject to revalidation if/when the population changes.

There are no hard deadlines in the CON process. Committee voted on deadline lengths, in days.

Committee asked, who can file an appeal? *Reference: Current regulations, pg. 17 at bottom of page (item #15). Must prove you are truly adversely affected party in order to file an appeal. If you don't prove you're adversely affected there may be a consequence. Committee decided that the burden is on the appellant.

Who has the authority to enforce? The Commissioner should have the authority.

Committee requests that the state clarify: Appellants should have to prove they're providing "similar" services (make less vague). Recommendation to state: clarify what is "similar"

*Small and large communities discussion was reintroduced.

Threshold Discussion

Comments from CON Committee members:

- -Facilities threshold should be increased (same for small and large communities).
- -Laws should be passed requiring physician's offices – or those practicing medicine have to serve all comers (all patients regardless of whether they have insurance or are able to pay).
- -Everyone seems to want to protect smaller communities and let larger communities have competition.
- -How does state determine need? Will the state count capacity of those outside CON when making CON capacity decisions? (this is recommended by the committee; as a way of collecting current data regarding the capacity of a community)
- -Smaller community hospitals don't have cath labs or oncology, etc. so need added protection from competition.

Facilities Threshold: Could make a recommendation to state to differentiate thresholds for large and small communities.

Equipment Thresholds:

Recommendation: state needs to clarify definition of equipment – differentiate between facility equipment and medical equipment (#2 on page 18) via an advisory group (see below):

Advisory group	Clearly define the differences between which items require CON <ul style="list-style-type: none">• Refurbished equipment (no CON)• Novel scope of services (possible CON)• Replacement equipment<ol style="list-style-type: none">a. Same purpose (no CON)b. New equipment (no CON)
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Facilities Thresholds:

Recommendation: state needs to clarify definition of facilities

Advisory group	Clearly define the differences between which items require CON <ul style="list-style-type: none">• Refurbished, remodeling existing facilities, renovating and/or repairing existing facilities for same use, same scope of services- no added services (no CON)• Novel scope of services (possible CON)• Replacement facilities<ul style="list-style-type: none">a. Same purpose (no CON)b. New facilities (no CON)
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Committee Members Present November 20, 2007:

- | | |
|---------------------------------|--|
| 1. Ward Hinger | 13. Vicki Crumptoula (for Creed Markunian) |
| 2. Jeff Kinion | 14. Baxter Burton |
| 3. Robert Bridges | 15. Gerald Nicholson |
| 4. Chakri Inampudi | 16. Jeremy Hayes |
| 5. Lester Lewis (for Brad Cruz) | 17. Bruce Jayne |
| 6. Shawn Morrow | 18. Jim Jordan for (Ross Tanner) |
| 7. James Shill | 19. Rod Betit |
| 8. Paul Morris (for Ed Lamb) | 20. Victor Joseph |
| 9. Al Parrish | 21. Jay Butler |
| 10. Mike Powers | |
| 11. Norman Stephens | |
| 12. Ryan Smith | |

Session 3 CON Committee Meeting Notes: November 20, 2007

HOPES

- Discuss 1 & 5: 1 is ASCs. 5 is POE recommendation to differentiate ownership requirements for large and small communities
- Would like hospitals to be able to partner with physicians
- Empower state to have some teeth in compliance

CONCERNS

- Discuss Enforcement
- Discuss Follow up
- Quality - measures

Decision Considerations:

- Will it reduce litigation?
- Will it assist in cost containment?
- Will it assist in access?
- Does it level the playing field?

MORNING DISCUSSION NOTES (11/20/07 am):

Victor Joseph asked to remove Tribal Exclusion language from the agenda.

Comments from Committee Members:

- Technical (knowledgeable and impartial) advisory group should be utilized regarding equipment.
- State needs to fund a data driven process in order to avoid a litigious CON environment. It takes resources to collect data.

Litigation Overview (Kevin Henderson, DHSS):

9 appeals last year; 3 related to POE and Imaging Services, 3 related to ASCs, 2 related to RPTCs(??).

ASCs (in CON process) Discussion - 8:00am

- ownership: active vs. passive investor
- scope of practice
- in practice together
- common EIN

Comments from Committee Members:

- Is it for own use or is it a pool of physician's who go to hospitals. Physicians differentiate by coding.
- Suggestion: 100% ownership

FOLLOW UP/ENFORCEMENT Discussion - 8:30am

Comments from Committee Members:

- Enforcement on bigger issues: keep it simple so as not to create more unfunded mandates.
- Penalty for gross misstatements or lack of compliance. State doesn't have resources to provide follow up for each CON grantee.
- No ASC definition in Statutes or Regulations.
- P.O.s should still have to submit a letter of determination to the state; the letters will provide data to the state which will help in determining need for CON applicants.
- There should be a mechanism that shows whether an MRI (etc.) is running at capacity.
- Count everything in a community when looking at need.
- capacity needs to be defined for this discussion. 600 CT scans for our office vs. 30,000 at Providence.
- Confidentiality of data submitted should be maintained.
- The group is not addressing purpose statement that was addressed on day one, so the group might as well throw out purpose statement.
- When we are talking about POE imaging modalities we will never come to a collective understanding.
- If there is a timely review and appeal process along with clear definitions, loopholes will be decreased.

POE Ownership for P.O. Exemption Discussion – 10am

Comments from Committee Members:

- Hospitals in large communities need to partner with imaging (for POE).
- If hospitals can partner with radiologists (radiology office exemption) there is a negative consequence that hospitals can play favorites.
- We voted before and decided that hospitals could partner and it was 83% yes, I'm surprised we're back discussing this issue again.
- Shows the need to split between large and small communities.
- How much competition can you put into a community without creating adverse affects?
- Concerned about a level playing field.
- I have shifted and have resigned to the fact that I'll have radiology centers.

- Physicians' don't have the ability to threaten hospitals as they are small entities. If we say yes to allow hospitals to practice in P.O.E. which was made for physicians. There shouldn't be a loophole for hospitals and/or large entities.
- From a legal standpoint, makes sense to make consistent ground rules. 100% for small communities then make it 100% for large communities. Make it the same across the board for ease of managing the process.
- Consistency to eliminate loopholes.
- Allowing abuse: number between 50% ownership. If forced to agree on a number, might find consensus. How easy is it to abuse? 50% is easy to abuse. Can we come up with a number to limit abuse?
- Process concerns: hope this is the last time the CON committee has to meet in the next 15 years. Drivers: Healthcare environment and an expectation of greater immigration between hospitals and primary care. Primary care is struggling and will probably go away eventually.
- See change in healthcare. In Maine 2/3 of new graduating medical students are employed by hospitals. Agree about the standards. There is a distinct difference between large and small communities. Small communities can be adversely affected. If there is going to be a CON process, should have to prove, through data, that you're (the state) doing what you set out to do (cost control, etc.). POE ownership: makes no difference in a large community.
- Every step we've said let's reduce competition. Hospitals need to embrace new competitors. CON reduced to competitive barriers to anything new in the state. Don't think there should be any restrictions. Don't see the difference between hospitals and any other businesses. Should be open to anyone.
- There is a need for some type of hospitals to work together. Geographic issue has come up.
- Either 100% physician owned or should be able to partner with anyone.
- 100% physician owned
- Level and consistent process
- Do see loopholes. All go through P.O.E. process.
- Level the playing field and create consistency in the P.O.E. application process. Everyone wants to level the playing field. Make the process crystal clear with rules for the Commissioner to follow. Have an issue with hospitals partnering with physicians. It's ok for physicians to partner with physicians.

Last vote on P.O.E. Exemption. Meeting adjourned at 3pm.

See attached excel spreadsheet

