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STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED

PUBLIC HEARING
REVIEW STANDARDS FOR COMPUTER TOMOGRAPHY (CT) SCANNER SERVICES
DENTAL CT SCANNERS

BEFORE ANDREA MOORE, DEPARTMENT TECHNICIAN TO C.O.N. COMMISSION

201 Townsend Street, Lansing, Michigan

Monday, July 24, 2006, 10:00 a.m.

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1 Lansing, Michigan

2 Monday, July 24, 2006 - 10:02 a.m.

3 MS. MOORE: Good morning. I am Andrea Moore, and
4 I am a departmental technician to the Certificate of Need
5 Commission from the C.O.N. Policy Section of the Department
6 of Community Health. Chairperson, Norma Hagenow, has asked
7 the Department to hold the public hearing today.

8 We are here to take testimony regarding concerns
9 for potential language revisions to the Certificate of Need
10 CT Scanner Services Standards. The Standards for CT
11 Services are being reviewed and modified to include, but not
12 limited to, the using 200 dental CT images for the
13 initiation number based upon dental procedures performed in
14 the preceding 12-month period; using 200 CT equivalents for
15 a maintenance number after initiation and annually,
16 thereafter; demonstration of training and/or certification
17 of dentists and dental CT operators; adding a research
18 exemption language for dental CT applications such that
19 someone who wanted to acquire a machine with 100 percent
20 research would not be required to meet initiation and
21 maintenance volume numbers.

22 Copies of the proposed changes to the standards
23 are located on the back table. Comment cards are also found
24 back there. We would ask that you would sign in and
25 complete a card if you wish to provide testimony. You would

1 hand the card to me, and if you have written testimony, if
2 you would provide a copy of that to me at the end of your
3 comment time.

4 As indicated on the Notice of Public Hearing,
5 written testimony can also be provided via our website at
6 www.Michigan.gov/con until 5:00 p.m. on Monday, July 31.

7 Today is Monday, July 24th, 2006, and we will go
8 ahead and start taking public testimony. And we're going to
9 start this morning with Dr. Sharon Brooks.

10 DR. BROOKS: Thank you very much for this
11 opportunity. I'm Dr. Sharon Brooks. I'm at the University
12 of Michigan. I am the user of an i-CAT CT -- dental CT
13 scanner. I'm not the owner because it's owned by the
14 regents of the University of Michigan, but I'm its user.
15 And I would first of all like to go on record -- and I did
16 mention this at the last C.O.N. meeting -- that I'm not
17 convinced that there is a need for regulating dental CT
18 scanners in the State of Michigan because of their
19 difference from medical scanners, including being only
20 one-tenth the cost. And they are, in general, just
21 replacing standard dental imaging. But I also understand
22 that there is an interest in regulating these, and so I'm
23 going to, then, address my comments to the proposed
24 regulations.

25 The first one that I have -- and I have put my

1 comments in order that they are in the document -- is in
2 Section 2, Number (1)(L), which is definition of dental
3 procedures that can be facilitated by dental CT images. And
4 there is a list of proposed procedures, including dental
5 implants, wisdom teeth, surgical procedures, other surgical
6 procedures and temporomandibular joints. I have no problems
7 with any of those. What I do feel is that this list is
8 incomplete in that it does not contain one of the most
9 commonly used reasons for doing dental CT. And that is for
10 evaluation in the third dimension for orthodontics. And I
11 believe there are some other people here in the audience who
12 will be speaking to that. I feel that to leave this
13 important use out of the approved list of dental procedures
14 is forcing Michigan dentists to provide care without the
15 diagnostic tools that are the standard of care in other
16 states.

17 The second area that I would like to comment on is
18 Section 4(3), which is the operating level for initiating
19 operation of a dental CT scanner. The medical level is at
20 7500 CT equivalents. And the proposed number for dental is
21 200 per year. And I think that this is not a realistic
22 number for the machines that will be in a private practice.
23 It is a realistic number for a dental institution like the
24 University of Michigan or the University of Detroit Mercy,
25 but dentists in private practice who are acquiring this

1 machine may find it difficult, at least at the beginning, to
2 meet a number of 200. And if they are required to do so, it
3 may lead to inappropriate use and increased health care
4 costs. And so I would recommend that the number be placed
5 at 100, which I think that anyone who buys a machine should
6 be able to reach.

7 The next area that I'd like to comment on, Section
8 4, Number (5), which is on page 3 of the proposed
9 regulations, and that is on the training for dentists who
10 interpret the images. And I do have some -- I will give you
11 my full written thing, and I'm not going to just say it all
12 here, where I give the description of why I think there are
13 some issues. I think the wording as it is is vague. And I
14 have proposed some new wording for that section which I will
15 read. And this is to replace Number (5), which is on the
16 interpretation of the images. I don't have a problem with
17 the paragraph on the taking of the images.

18 "The applicant has demonstrated to the
19 satisfaction of the Department that the dental CT
20 images generated by the proposed dental CT scanner will
21 be interpreted for pathology by either a licensed oral
22 and maxillofacial or medical radiologist or by a
23 licensed dentist who has received training in
24 interpreting dental CT images for pathology from an
25 oral maxillofacial or medical radiologist.

1 Training and using the dental CT images for the
2 purposes they were taken, for example, evaluating the
3 amount of bone available for dental implants, must also
4 be obtained from a source acceptable to the Department
5 including courses in an accredited dental school, a
6 continuing education program certified by the American
7 Dental Association or an appropriate professional
8 society that provides such courses for its members."

9 And basically, I have divided up the
10 interpretation into the disease versus the dental reason for
11 taking it. There a couple other spots where training and
12 the numbers are mentioned, and it's basically the same
13 change all the way through.

14 Section 13(1)(D)(VI)(C) on maintaining information
15 by payer and non-paying sources to indicate the volume of
16 care from each source provided annually -- and I realize
17 that this is part of the medical standards -- this is
18 generally not required for other types of dental imaging,
19 including panoramic, cephalometrics and such. And it does
20 seem like an unnecessary bureaucratic requirement that will
21 not enhance the delivery of dental care, and I recommend
22 deletion of this section.

23 Similarly, Section 13(1)(D)(VII), "The applicant
24 shall participate in a data collection network established
25 and administered by the Department" -- and it goes on for a

1 long time -- this is obviously designed for a very busy
2 hospital imaging center. It is not relevant to the use of
3 dental CT imaging in a private dental office. The time
4 spent collecting such information which is not routinely
5 done in dental offices will add to the cost of health care
6 without obvious benefit to the patients or to the State.
7 Deletion of this section is recommended.

8 Section 13(1)(D)(X), requirement for participation
9 in Medicaid, currently dentists are not required to
10 participate in Medicaid in Michigan, and the majority of
11 dentists do not participate. The types of dental procedures
12 that dental CT scans are performed for are not services
13 covered by Medicaid, such as dental implants and
14 orthodontics. And requiring a practitioner to participate
15 in Medicaid in order to use a dental CT scanner when such
16 scans and the procedures they're used for would not be
17 covered at all by Medicaid is not reasonable.

18 Section 11 and Section 13(4) on the dental CT
19 scanner used solely for research, there are only two dental
20 schools in Michigan, the University of Michigan and the
21 University of Detroit Mercy. It is unlikely that either
22 institution will be able to obtain enough research grants to
23 completely cover the cost of a dental CT scanner dedicated
24 solely to research without any recourse to at least partial
25 payment by patient or third-party payer or the potential for

1 non-research uses also. It's just a comment.

2 And then the last comment is on Section 16(2) and
3 (3) which is documentation of the number of procedures
4 performed in the previous 12 months. This section penalizes
5 dentists who have recently completed their training programs
6 in which they used dental CT for procedures but have not
7 personally performed enough procedures in their newly
8 established office to qualify to purchase a dental CT
9 scanner. And those are the -- that's the end of my
10 comments.

11 MS. MOORE: Thank you very much. Next we'll have
12 John Schondelmayer.

13 DR. SCHONDELMAYER: All right. Can everyone hear
14 me? Good. I got a couple of handouts at the back table.
15 One was this half-page outfit (indicating). Another one is
16 a single page. I'm a private practitioner in White Cloud,
17 Michigan. It's about an hour north of Grand Rapids. I
18 bought a NewTom in December and January of this year, and
19 shortly after I had it, I found I couldn't use it. And I
20 paid payments for the first four months without being able
21 to use it. So I guess you can imagine I've had to shift
22 gears and change a lot of the way we do business for a
23 little while.

24 I want to start out just with a little brief
25 history about myself. I'm the end user for a lot of these

1 machines. I'm in a small practice in a small town. It's
2 the town I grew up in. All my friends and family live
3 there, and that's who I've worked for all my career. I've
4 been in business for 25 years. I started out in 1981, and
5 the interest rates then were 17-1/2 and 18-1/2 percent. The
6 first loan I had was 65,000 bucks. I bought my whole
7 practice. And it was tough. The first three years we lost
8 money. Our debt went up every year. And the first thing we
9 had to do was stop doing Medicaid.

10 I lost a lot of friends then, people -- I had to
11 say, "Hey, I can't treat you anymore 'cause I can't afford
12 to." I felt pretty bad. And over the course of time we
13 found that a lot of people had to drive to go to see
14 specialists. And we could get continuing education and
15 learn some of these things and provide services. Otherwise,
16 you know, they couldn't get it or they just wouldn't drive
17 for. And that's how we survived over the years. We added
18 orthodontics, all types of oral surgery, except for the
19 major oral surgery, periodontics, endodontics, everything.
20 We went to school. We learned how to do everything so we
21 could help people in that small area.

22 We live in Newaygo County. It's, I think, the
23 second poorest county in the state, but we've made a go of
24 it there; been there a long time. My dad used -- my dad
25 just passed away this summer. He used to always tell me how

1 proud of me he was that I didn't file bankruptcy because
2 there were a lot of times when it would have been a lot
3 easier to just walk away. I didn't do it. We stayed in
4 business. And, you know, with this NewTom deal, I kind of
5 feel like I'm back in the same position. I've got a huge
6 debt, 180,000 bucks to buy this machine. And we added
7 implants last year. We didn't know we needed a Certificate
8 of Need. Last year my associate and I went to school. We
9 each put in 170 hours of continuing education. We went to
10 Chicago and got a lot of training and got already to go with
11 implants. We realized we had to use this machine to really
12 make it a safe procedure. And we started out with using the
13 hospital CT scans, and we ran into a major road block there
14 because the hospital units were costing the patient 1100
15 bucks plus the radiologist's fee on top of that. And
16 patients were just stopping dead in their tracks and just --
17 it stopped them right there.

18 And so we looked at, "What else can we do?" We
19 thought, "Well, let's see about buying a CT scanner." So we
20 did that, and now we got the cost down to \$127 for a scan
21 and no radiologist's fee. And we started using it for
22 implants, and that's helped out a lot. And then we realized
23 that it's just wonderful for orthodontics. And if you look
24 at that little hash sheet right there (indicating) -- most
25 of you have seen these images -- that's just my last ortho

1 patient. I didn't pick the toughest one or anything like
2 that. It's just the last one. And I'll tell you what,
3 looking at the black-and-white stuff that we could
4 traditionally get with two-dimensional film-based stuff
5 couldn't sort that out. There's no way. And most
6 orthodontists in my area don't have that equipment. And I
7 know some of it are starting to buy it. But when you can
8 get a three-dimensional image like that and really see
9 what's going on, you can do them some good.

10 So enough about my history. I wanted to mention a
11 little bit about the economics in a dental business. Most
12 of our money for the CT scanner does not come from insurance
13 companies. I know that one of the guys in on some of the
14 talks represents one of the major insurance companies in the
15 state, and they're a major payer for us too. We have about
16 half of our patients with dental insurance. Half of those
17 are Delta. Blue Cross is another big portion, maybe 35
18 percent, and the rest are all distributed among several
19 hundred companies.

20 Most of what we find is that our cash patients
21 actually carry some of the insurance patients. I actually
22 take money out of my pocket to perform certain procedures
23 for Blue Cross. Like if I do a denture, for example, I'm
24 going to write off 45 percent of the fee. It costs me more
25 to do that work than it does -- you know, than the patient

1 gets -- than the insurance company will pay for it. But we
2 do it to get to the other work. Extractions, there's no
3 overhead on extractions, so it kind of works out overall.
4 But the point is that the -- whenever you start shutting
5 down the cash procedures, you say, "Okay. Some dentists
6 can't get CT scanners," that's how they pay for some of the
7 insurance work, honestly.

8 If anybody's going to do Medicaid, some people
9 will do it out of a humanitarian feeling, and they'll do
10 maybe ten percent of their practice. And the fact is that
11 the other people are paying for it. We're not a federally
12 subsidized office, and, you know, it takes that to make that
13 work. Our overhead is 75 to 80 percent, just to give you a
14 number. So when we write off 45 percent on -- we couldn't
15 make a living. We couldn't be a denture clinic for example.

16 Speaking of humanitarian work, I want to talk just
17 a little bit about how the C.O.N. application process has
18 changed my life. And I'd sure like to see this streamlined
19 in the future. We started out by being surprised we even
20 needed one. We just called up to get a radiation permit,
21 and they said, "Oh, no. You've got to have a C.O.N.
22 permit." I didn't know what it was. I was quite ignorant
23 about the whole process, and through the course of events,
24 we ended up making four or five payments, like I said,
25 without having any income from the machine or being able to

1 use it.

2 And then you guys did come to my rescue, and I
3 certainly appreciate it. We've been allowed to use it for
4 dental purposes, and it's been a joy. I spent about four to
5 six hours on the application itself. I finally gave up.
6 It's like fitting a square peg in a round hole. I hired
7 somebody to help me. It cost me almost \$4,000 to have an
8 accountant with experience trying to set it out. It cost me
9 \$1500 for the application. At my fees for 127 bucks per
10 scan, I've got to take 43 scans just to pay for the
11 application process. I'd sure like to see all that change
12 to make that whole thing a lot easier at some point.

13 I missed -- I've had to cancel two mission trips
14 to Africa, so this affects my personal life and my
15 professional life and what I do for other people. I've been
16 going to Mexico or Africa for three, four years. I've had
17 to cancel those trips through this process trying to get
18 this sorted out, and I'd sure like to see it resolved.

19 Probably the biggest thing I want to say, that I'm
20 categorically opposed to this type of regulation for
21 dentistry. Nevertheless, I'm going to go along with it and
22 make my recommendations on that single-page sheet. If we've
23 got to be regulated, I appreciate the chance to say
24 something about it. I guess my biggest fear is that here I
25 am with Big Brother telling me I might not be able to

1 provide the standard of care that I morally and legally
2 should provide to my family and friends.

3 Now that I've used the machine, I can see where
4 it's vital. And I know that nobody argues whether it's
5 important or useful, but I'd sure hate to be put in a
6 position where I can't use it or my colleagues can't buy one
7 because we're going to restrict how many can have it and how
8 many small offices out in the outlying areas might not be
9 able to demonstrate from their own practice the numbers that
10 are needed when nevertheless, three or four offices could
11 get together and come up with the numbers. So I'm hoping
12 the regulations will allow that type of collaboration.

13 In my practice -- I'm glad that you had -- Dr.
14 Brooks, you had mentioned those comments on the suggested
15 guidelines. I would not be able to provide Medicaid
16 coverage. I don't do it now. I just simply can't afford
17 it. I can't have it on there. It would not work for us.
18 No way in God's green earth could we afford that. And
19 besides that, there's a huge clinic right next door that
20 does do it, so there is care, and people are getting taken
21 care of there.

22 To go to my one-page sheet, we've talked about
23 most things on there. I just want to highlight Number 6 on
24 there. Probably two important uses are for -- one is oral
25 pathology. We don't do that very often, but we've found

1 it's absolutely unbelievable how much better we can diagnose
2 certain things that we haven't been able to diagnose any
3 other way. I've had failed -- specifically failed root
4 canals. I had a patient go have a hospital CT scan. She
5 paid the money for it. It was a huge amount of money. It
6 wasn't covered because it's for a dental procedure. We
7 could not visualize what was wrong. We took the scan with
8 the NewTom CT scanner, and it didn't take long to figure it
9 out. She had a problem with a root canal. We could prove
10 it, and we knew we needed to take the tooth out. So to
11 force a practitioner into the hospital CT scan situation is
12 not going to be good for patients.

13 The other thing, orthodontics -- I already told
14 you about this (indicating) half sheet -- it's unbelievable
15 how well you can sort out the teeth when you can see them
16 three dimensionally when they're still in the bone. This
17 little girl needs intervention, and there's just no way you
18 could have sorted that out or figured out a treatment plan
19 without a good cone beam CT scanner. And her family
20 couldn't afford -- they're low income. Am I going to send
21 them to a hospital? They can't afford that. \$127 at my
22 place. They just can't afford it. I don't know what to
23 tell people like that.

24 And then the other thing I put down on my --
25 everything else is self-explanatory. Point number 8, we

1 just realized that -- we do five-year radiographic exams,
2 mostly for young people. It's a panoramic style of an
3 image. It's recommended every five years. And what we
4 found is that it really turns out to be an orthodontic
5 preventative type of a procedure. You're looking to make
6 sure they don't have a problem developing that you could
7 help by doing some PO extractions to help the teeth come in
8 straighter right off the bat. I didn't see that on any of
9 the guidelines, and I would suggest that that's added.

10 I suppose we could call it an orthodontic scan,
11 and that's what it's for. But there's a lot of
12 troubleshooting that you can help with like with traumatic
13 bone cyst and that type of thing. If you could find enough
14 scans, it would be darned good procedure to incorporate in
15 that list of procedures that we're going to allow. Any
16 questions? Okay. That's it for me. Thank you for your
17 time.

18 MS. MOORE: Thank you. Next we're going to have
19 Don Tyndall.

20 DR. TYNDALL: Tyndall (pronouncing).

21 MS. MOORE: I'm sorry.

22 DR. TYNDALL: That's fine. First of all, I'd like
23 to thank the Commission for allowing me the opportunity to
24 provide this information. I'm going to give a little
25 background about myself, and please don't be put off. I'm

1 not trying to impress anybody, but I thought it might be
2 useful that you know something about my background and
3 qualifications to speak to these issues. Several of the
4 issues raised by the standards fall into an area I've much
5 expertise with over the years, so I'm just going to give
6 everyone a brief introduction to my background since most
7 people probably don't know me.

8 My name is Don Tyndall from the University of
9 North Carolina School of Dentistry. I'm currently professor
10 in the Department of Diagnostic Sciences and General
11 Dentistry and director of the Oral and Maxillofacial
12 Radiology Division. I serve as director of our graduate
13 program in oral and maxillofacial radiology for 13 years,
14 and was a member of the North Carolina Radiation Protection
15 Commission for 16 years. I have served on the Executive
16 Council of the American Academy of Oral and Maxillofacial
17 Radiology as counselor for scientific affairs and am the
18 past president of the American Board of Oral and
19 Maxillofacial Radiology.

20 I recently completed a six-year term on the
21 Radiology Review Committee of the American Dental
22 Association which is responsible for creating accreditation
23 standards for the specialty of oral and maxillofacial
24 radiology as well as accrediting graduate training programs
25 in the discipline. So that's enough of the background.

1 I've been asked by Sirona Dental Systems to
2 provide expert commentary on the proposed Certificate of
3 Need Standards for dental CT scanner services in the State
4 of Michigan. We've been using a cone beam dental CT unit,
5 the NewTom, as previously mentioned. We've been using these
6 services for four years at the UNC School of Dentistry.

7 Now, just in a general comment I'd say this has
8 been a great benefit to the patients at our school. The
9 number of applications for this very innovative technology
10 continues to increase. Each week and month we're finding
11 new applications for this very interesting technology.
12 We're finding that it has in many cases resulted in fewer
13 complications, less time in therapy and recovery from many
14 dental treatment procedures. I will limit my comments to
15 the proposed changes for dentistry CT that are in the upper
16 case letters on the Certificate of Need document for today's
17 hearing.

18 Starting with Section 2 under "Definitions,"
19 subsection (L), the list for dental procedures, I don't
20 believe, as previously discussed, is not inclusive enough.
21 And I would recommend that a list be expanded to either say,
22 "Include a majority of dental procedures that would normally
23 require radiographic imaging," or expand the list to include
24 orthodontic, periodontal, endodontic applications as well as
25 oral pathology.

1 A rationale for this is that recent advances in
2 this technology both current and in the near future of these
3 dental CT systems will enable these systems to perform
4 three-dimensional imaging of the teeth and jaws for
5 periodontal disease, pulpal disorders -- and already seen a
6 good example of that -- and perhaps even for detecting
7 cavities more effectively. We recently used our dental CT
8 system to diagnose root fractures, pulpal disease, internal
9 resorption of teeth that were not discoverable by
10 conventional radiographic or clinical means, saving the
11 patient time, money and discomfort. The newer systems may
12 have even higher resolution capabilities for these common
13 dental applications.

14 Our orthodontists have found that CT imaging can
15 provide useful and significant three-dimensional information
16 regarding orthodontic therapy. Many of our oral surgeons
17 have found that location of the nerve canal in relationship
18 to a wisdom tooth with dental CT imaging has often prevented
19 surgical complications which could have resulted in nerve
20 damage to the patient.

21 We have been doing quite a bit of research in this
22 area at the University of North Carolina, as have many other
23 institutions. And this has shown that dental CT systems can
24 be used to derive the same images used for orthodontic
25 therapy, both panoramic and cephalometrics images, as

1 accurate or more accurately than conventional means. In
2 fact, dental CT derived panoramic images are free of the
3 distortion and the magnification that accompany current
4 panoramic systems and could be used in place of conventional
5 panoramic systems for most dental applications.

6 So single-scan imaging the patient could also save
7 time compared to conventional intraoral x-ray imaging and
8 potentially produce more useful information to the patient's
9 benefit. What I'm saying is, this technology is advancing
10 to the point that it may be possible in the near or
11 certainly moderate-term future to replace much of the
12 intraoral imaging now done by conventional means so that the
13 patients don't have to have devices placed in their mouth
14 and we have the imaging problems that occur from that.

15 Now, most people I've talked to, both patients and
16 practitioners, have said an ideal dental imaging system would
17 be one where nothing is placed in the mouth. It's more
18 comfortable. It doesn't take as much time. It's not as
19 technique sensitive. And it's possible. The way current
20 research is going, it certainly suggests that these scanners
21 may be able to replace most applications in dentistry. I
22 don't think we're quite there yet, but I think in writing
23 standards you want to look at little bit to the future as
24 well.

25 Now, in Section 4, the requirements of approval of

1 applicants proposing to initiate a dental CT scanner device,
2 and speaking with regard to subsection (3) where 200 images
3 per year are being asked, I think at this time it's
4 excessive. And I would recommend a starting figure of 100
5 images per year. The rationale for this would be, while
6 technology suggests -- advances in technology suggest that
7 there may be multiple uses other than what is listed in the
8 current standards, the Certificate of Need standards should
9 not be based on these potential applications but rather on
10 current practice.

11 At the UNC School of Dentistry we see about 400
12 cases per year with our dental CT system. This is including
13 pure research -- or excluding pure research cases. And we
14 have about 80,000 patients of record at the school, but I
15 would not expect a private office to be able to produce half
16 of the number that we're producing, as I've said currently
17 is about 400. So I think the 100 mark is a good one
18 certainly for a starting point. It's very reasonable.

19 Now, in subsection (4), there's a CT machine
20 operator qualifications. These systems are fairly easy to
21 operate, and a dental assistant or hygienist with
22 appropriate training could be used to operate the machine.
23 Dental CT machine operation is really no more and perhaps
24 even less complicated than that of current panoramic systems
25 which dental assistants and hygienists can operate

1 effectively with adequate training. The difficulty in
2 operation comes in constructing the images and interpreting
3 them, and that would be out of the purview of the hygienist
4 and dental assistants.

5 So we're down to subsection (5) and
6 interpretation. So while operation and image acquisition of
7 dental CT images does not require much training, the
8 interpretation aspects -- which consists of two parts, image
9 reconstruction and reading of these results for the
10 particular purpose like dental implants and orthodontics
11 purposes, but there's also a second part of the
12 interpretation: Is there any disease present that wasn't
13 discoverable by a conventional means or a clinical means?
14 So I think it does require some advanced training. The
15 question is, how much?

16 Well, this section of the standards is correct in
17 stating the applicant should demonstrate that images
18 produced by the unit be interpreted by a licensed dentist
19 trained or certified by one of the three groups mentioned.
20 The question is, how much is enough? Well, as I mentioned
21 earlier, there are two types of interpretation required:
22 One for the construction and reading of the images useful in
23 diagnosis and treatment planning of specific dental or
24 surgical procedures. The second type of interpretation is
25 needed to evaluate for pathological changes and

1 abnormalities that may have an impact on the patient's oral
2 or general health.

3 Because dental CT technology provides greater
4 clarity of the maxillofacial complex, diseases or
5 abnormalities previously unseen by conventional radiographic
6 means may be visualized. This is not an everyday
7 occurrence, but we are seeing at our school cysts,
8 occasionally tumors or other conditions, impacted teeth that
9 are way back in the palate area that would otherwise not be
10 seen by a clinical or conventional means. So this is
11 something that does come up, and I think dentists should
12 have some level of training in recognizing -- if not the
13 interpretation of what the entity is, certainly should
14 recognize when, "Something is unusual here. I need to refer
15 it to a specialist."

16 So I would recommend that each applicant, whoever
17 operates these machines, review all the scan data, not just
18 the part they're looking for the particular treatment, and
19 send questionable cases to certified oral and maxillofacial
20 radiologist for interpretation. And there are a number of
21 various schools. We have two schools here in Michigan.
22 There are schools throughout the country that have
23 radiologist capable of providing this service.

24 Of course, the dentist should be trained in CT
25 anatomy and also in the recognition of pathological

1 conditions revealed by CT data. I emphasize here that
2 recognition of an abnormality, not its interpretation -- I
3 wouldn't expect a general dentist to interpret a lesion, an
4 radiolucency in the jaws, but certainly recognize that
5 something's different here and they need to consult with a
6 specialist. So we'd recommend that this information be sent
7 to a radiologist to be read.

8 Now, I'd recommend that some sort of CD or
9 web-based program on CT anatomy be provided to the applicant
10 prior to or during or -- certainly probably before or during
11 a course of instruction. I've talked to Dr. Brooks about
12 this. I've talked to several colleagues of mine. How much
13 instruction is necessary? We think a full day under the
14 supervision of oral and maxillofacial radiologist would
15 provide at least a beginning point to make someone
16 adequately trained to recognize some of these abnormalities.
17 And I again would suggest perhaps prior to the course doing
18 a web-based CD or CD-based course on CT anatomy. So some
19 training we'd certainly recommend, but start at one day plus
20 a little bit more through the CD perhaps, and then, perhaps,
21 some recertification training every once in awhile as is
22 required of most dentists anyway to keep their license
23 for -- their dental license.

24 So Section 11, just a comment about dental CT
25 units for research. I do not think there will be very many

1 units falling into this category since these systems are
2 generally used for both research and patient care at schools
3 of dentistry. As Dr. Brooks mentioned, it would be very
4 unusual to find enough grant money or grant participation to
5 pay fully for the cost of these devices. So my guess is
6 that most schools and research areas are going to want to
7 use these for both.

8 Then finally in 13, subsection X, this section
9 appears to require that the applicant treat Medicaid
10 patients. I find little rationale for this since many
11 dentists do not accept Medicaid patients. This has been
12 adequately illustrated by the previous speaker. Operation
13 of the dental CT unit should be independent of Medicaid
14 acceptance. These units by and large are not going to be
15 located in hospital environments where such a standard may
16 be appropriate.

17 In summary, I support the use of these dental CT
18 devices in the hands of our perfectly trained dental
19 practitioners. I believe based on our four-year experience
20 with dental CT systems and research that usage of dental CT
21 technology has produced better patient care resulting in
22 less treatment complications, faster surgery times as well
23 as recovery from surgery and more accurate orthodontic
24 assessment and an overall improvement in the diagnosis and
25 therapy of dental diseases. In the long run this type of

1 imaging could lead to less loss of work time and actually
2 lower the cost of health care in many cases. Once again, I
3 thank you for this opportunity to present this testimony.

4 MS. MOORE: Thank you. Next we'll have Barbara
5 Jackson.

6 MS. JACKSON: Good morning. I'm Barbara Jackson,
7 Economic Alliance for Michigan Regulatory director. One of
8 my responsibilities is Certificate of Need administrative
9 issues, and there have been a lot of administrative issues
10 over the past few years. Our organization is a statewide
11 coalition of various businesses that includes auto
12 manufacturers, suppliers, retail service and banks plus the
13 full breadth of the private sector labor movement.

14 First of all, we want to commend the Commission
15 for its deliberative process in establishing modified
16 standards to assure timely availability of this new
17 application. The proposed standards were unanimously
18 approved at the June 21st C.O.N. meeting, and we just wanted
19 to note that this vote reflected the support of all
20 commissioners, which includes the consumer, payer, provider
21 and purchaser perspectives. We again commend the Commission
22 for its development of this balanced standard and want to
23 emphasize that this language for CT for use for dental CT
24 significantly differs from the requirements for the
25 full-body CT scanner.

1 Minimum volume, the full-body scanner requires
2 7500 unadjusted scan procedures. The tentative 200 annual
3 scan threshold is a placeholder, and we -- in fact, higher
4 and lower numbers are being discussed, but all these numbers
5 are significantly less than the 10 percent of the 7500
6 required for full-body scanners.

7 In terms of training requirements, full-body CT
8 scans must be evaluated by trained physicians. Dental CT
9 language permits dentists to evaluate the scan following
10 necessary but limited training on this new technology. We
11 think it's appropriate for patient needs. C.O.N. provides a
12 mechanism that allows promotion of the State's
13 responsibility for affordability, quality and accessibility
14 of health care services.

15 And then in terms of quality via training
16 requirements, the standards addressed modest yet necessary
17 assurances of training and competence for health
18 professionals' use of this technology including the
19 technicians who operate the machines, those who interpret
20 the scans and those who use the scans to perform the
21 specified dental procedures. The expectation is that brief
22 training sessions will be required with less time for the
23 technicians than for the dentists interpreting and using the
24 scans, as other folks have stated. As Dr. Brooks and Dr.
25 Tyndall said, I mean, we think that, based on what we've

1 heard, that a full day or a few hours over a period of weeks
2 would be sufficient as a baseline. And we think that sounds
3 right.

4 Quality measures that generate appropriate volume
5 for ongoing proficiency: Appropriate minimum annual volumes
6 assure technicians and dental specialists utilizes
7 technology frequently enough to maintain proficiency. So we
8 do support implementation of appropriate minimum volume
9 thresholds as to assure the proficiency and also for cost
10 effective utilization means. The proposed standard is 200
11 annual scans which breaks down to only 4 studies a week. At
12 the June meeting we stated that the volume threshold should
13 be increased to assure enhanced cost effectiveness. Our
14 organization is still reviewing relevant issues. We believe
15 that the required volume should be in the single-digit
16 percentages of the 7500 requirement for a full-body scan.

17 Cost effectiveness versus minimum volume: C.O.N.
18 continues to be the one means to assure cost-effective
19 utilization. About half the dental scanners currently in
20 place in Michigan are not expected to be in dental offices
21 but to serve as freestanding dental imaging centers. We are
22 a group of businesses and unions, and we're concerned about
23 health care costs. And we are focused on the total cost of
24 health care, whether borne by the employer, government or
25 the individual, which, in the case for dental CT's,

1 individuals are going to bear much of the costs as is
2 spoken. Those are still costs. I mean, we still pay for
3 those.

4 We applaud the Commission for establishing a
5 standard that allows the immediate diffusion of this
6 technology yet implements minimum requirements that prevents
7 this technology from immediately becoming a kind of a
8 standard practice item. We're worried that this could lead
9 to over utilization and self-referral for this imaging
10 technology with inappropriate applications and turn out to
11 be far more expensive than the current imaging technology
12 for the patient.

13 Again, our health policy group discussed this
14 draft standard again, and we're still reviewing volume
15 thresholds in the application for orthodontics. And we're
16 just waiting kind of to see how it kind of rolls out and
17 waiting to hear what the experts think in those areas. And,
18 again, we commend the Commission for its action and bringing
19 this forward. Thank you very much.

20 MS. MOORE: Thank you. Next we're going to have
21 Richard Kulbersh.

22 MR. KULBERSH: I thank you for the opportunity to
23 speak on behalf of cone beam CT for dental radiography.
24 Just to let you know who I am, I am chairman and program
25 director of the Orthodontic Department of the University of

1 Detroit Mercy. And in the past year the University of
2 Detroit has purchased a cone beam CT. We have currently
3 integrated it with orthodontics, and we are taking our
4 radiographs for orthodontic diagnosis and treatment planning
5 using that machine. We feel that the technology certainly
6 allows us to do what we have not been able to do in the
7 past, which is essentially evaluate a three-dimensional
8 volumetric object in the way in which we can see internally
9 in terms of tooth position, impactions, relationship of
10 tooth roots to cortical plate, issues that are intimately
11 involved with orthodontic therapy and mechanotherapy.

12 In the past we have obviously used standard
13 radiography. We are now replacing that standard radiography
14 with cone beam technology. It allows us to, in a much more
15 simple and facilitated way, take all the images that we need
16 in orthodontics to appropriately evaluate the subject in
17 three planes of space. In the past, in order to do lateral
18 SEF's, PA SEF's, submental vertex as well as tomography of
19 the joint, required repositioning the patient numerous
20 times. Now, with one 20-second scan we are able to get all
21 that information. And it is true that it requires a
22 formatting -- reformatting session afterwards, but that's in
23 the hands of the people that are doing the diagnostics. And
24 from a practical standpoint, I'm not so sure that this is
25 going to raise costs in this respect.

1 To speak to the individual that spoke just a few
2 moments ago, for those schools and orthodontists that are
3 taking appropriate radiology to evaluate the craniofacial
4 skeleton in three planes of space, there's a cost associated
5 with repositioning the patient, taking the x-rays in all
6 those planes. And certainly, I'm sure the way insurance
7 companies are going to charge this out, that there will be a
8 charge for the scan, and then there will be probably a
9 reformatting fee or something of that nature. So actually,
10 in effect, the cost for the information in a cone beam
11 technology format will probably be less than what insurance
12 companies are currently paying for all that information
13 taken in the standard way that we now do.

14 So I would encourage you because of the new
15 information that we are uncovering and the ability to see
16 internally and discover those things that affect our
17 treatment biomechanics, not to limit cone beam technology
18 the same way you're limiting it in the medical environment.
19 Total exposure for cone beam CT for the types of things I've
20 talked about is probably one-tenth using a machine like the
21 i-CAT in comparison to conventional medical CT scanners. In
22 addition, if you look at how it facilitates diagnosis and
23 treatment planning, there is no comparison, as was discussed
24 earlier, between the types of x-rays that we currently take
25 and what cone beam radiology can do.

1 I want to further support but not go over all the
2 things that Dr. Brooks and Dr. Tyndall have said. I think
3 that they are critical with regard to the issues not only in
4 a dental school but also in private practice. In private
5 practice, the Medicaid issue is certainly something that is
6 not on the same level that it is with hospitals. The issue
7 of the number of scans per year I would also encourage you
8 to bring down to the 100 level. I think the training, as
9 has been mentioned, is entirely appropriate. And the
10 comments that have been made with regard to research, I also
11 agree that research funding certainly for universities is
12 very difficult to come by and certainly support of these
13 machines will also have to be done by their utilization. So
14 thank you very much, and if there are any questions, I would
15 be more than happy to address them if I can.

16 MS. MOORE: Thank you. Next we're going to hear
17 from Ed Goldman.

18 MR. GOLDMAN: Good morning. I'm Ed Goldman. I'm
19 a health care lawyer at the University of Michigan. I'm
20 also vice chair of the Certificate of Need Commission. The
21 university has an interest in dental CT technology, but I am
22 not here today to speak on behalf of the university, nor am
23 I here as an individual action of the Commission. As an
24 individual commissioner, I do want to explain what I believe
25 the Commission is trying to accomplish by seeking to

1 regulate specialized CT scanning.

2 As you've heard, originally the Commission had
3 regulations governing CT scanners. That was back in the day
4 when it was a general scanner. There are now specialized
5 scanners where the general rule, such as a minimum number of
6 scans per year, would not be applicable. The Commission
7 recognizes and applauds the efforts of Michigan companies to
8 create new technology in Michigan. The Commission doesn't
9 want to put any road blocks in the way of new technology,
10 but it is important, in accordance with the mandate for the
11 Commission, to evaluate and allow new technology in a way
12 that properly regulates cost, quality and access.

13 There is new CT technology not just for teeth and
14 jaws but also for head and neck and extremities.
15 Rheumatologists are looking at this technology. Orthopedic
16 surgeons are looking at specialized CT scanners. And so for
17 the Commission, specialized CT cannot meet general
18 standards, so each of these new applications needs specific
19 consideration. The Commission needs to consider all
20 specialized CT technology in seeking to implement proper
21 regulations.

22 Now, why do I say that? You are here today
23 looking at dental CT. The Commission has to look at a
24 broader scope of services. The Commission needs to
25 understand the new technology so that each of them can be

1 appropriately managed. For example, the Commission proposes
2 to drastically decrease the necessary number of yearly scans
3 for dental CT to a number where we will be informed, as we
4 are being informed today, by dental experts. We're looking
5 for what number is a reasonable number. We want those
6 professionals who need dental scanners to be able to obtain
7 them. We don't presently believe that every dental office
8 should purchase a scanner. Why? Because it would not
9 presently be necessary for patient access and would,
10 therefore, unnecessarily add to the cost of health care.

11 As you have heard from prior speakers, the
12 technology is going to evolve. If it does, the Commission
13 will revisit costs and revisit uses and reevaluate the
14 future need for regulation. It may be, as you have heard,
15 that this kind of technology will substantially replace
16 existing technology. If it does, when it does, the
17 Commission is prepared to revisit and look at this. How
18 will we do that? The Commission's work plan includes
19 establishment of a new subcommittee to investigate new
20 technology. And we'll be taking that up at, I believe, our
21 next meeting. The Commission at its next meeting will have
22 on its agenda final standards for CT scanners. Those
23 standards will be informed by public input such as we are
24 receiving at today's hearing and will be designed to meet
25 the needs of the citizens of Michigan.

1 I wanted to come today just to thank all of you
2 who are here today and those who have helped inform the
3 Commission so that we can do our best to properly manage new
4 and emerging CT technologies. I know the concerns
5 especially dentists in private practice have had with this.
6 It is not our intention to put road blocks in your way. It
7 is simply our intention to follow our mandate and try to do
8 what is appropriate. Thank you.

9 MS. MOORE: Thank you. Next we'll hear from Glenn
10 Melenyk.

11 MR. MELENYK: Good morning. I'm Glenn Melenyk, a
12 dental consultant from Blue Cross-Blue Shield of Michigan.
13 I'm not in official capacity representing what the Blue
14 Cross-Blue Shield legal policy is on CT scans; however, as a
15 dental consultant, I do help establish policy and with my
16 formal presentation will tell you what we will be covering
17 in the future.

18 We're not against new technology at Blue
19 Cross-Blue Shield of Michigan; however, we do need to be
20 responsive to our customers who are paying for what they
21 want to have their dollars most properly spent. When you're
22 doing new procedures there's a whole variety of issues you
23 need to look at, including this underwriting. How much is
24 it going to cost? How many people are going to use it? So
25 to throw a CT scan in as a covered procedure immediately is

1 very difficult.

2 The first question I'd like to ask is that, if you
3 had a procedure to do, be it orthodontics, an extraction, an
4 implant, and could not -- could honestly say that you could
5 not do that procedure without a CT scan, then I say the CT
6 scan is a valuable item and should be implemented. However,
7 for many, many, many of the procedures that are done every
8 day, the CT scan becomes unnecessary. What it amounts to is
9 that orthodontics for years and years -- although the CT
10 scan's giving you that three-dimensional image, orthodontics
11 has been done with the flat-plane technology. And kids have
12 some very nice teeth at the end of it. I was speaking to
13 our oral surgery consultant, and although he says the CT
14 scan would tell him exactly where that nerve is and where
15 those vessels are, if that tooth was symptomatic and needed
16 to come out, he would have to take it out anyway using all
17 of his dexterity and skill.

18 The use of dental CT scans has been established
19 under the rules. The scans are very useful when particular
20 anatomical landmarks and anomalies must be seen to ensure
21 the success of the treatment with the least amount of
22 complications. In my opinion, orthodontics at this time --
23 and this is what I'm saying, "at this time"; as we heard
24 earlier, that this whole thing will evolve -- does not fall
25 into this category. There will be a significant increase of

1 costs without a significant, again in my opinion, increase
2 of benefit or quality or access.

3 From a claims aspect, radiographic records which
4 I'll just limit to a panoramic and a cephalometric, which is
5 the standard which we receive and, from what I have been
6 told, the cost from people who out in the world use the CT
7 scans, is about 150 percent increase. My numbers are
8 that -- I have heard, that the CT scans, I have been told,
9 run from 500 to \$700, and we received that information last
10 time at our meeting. And typically the insurer will pay
11 approximately \$200 for a PAN and a cephalographic x-ray.
12 There are times where I feel that a CT scan is appropriate
13 in orthodontics, and this is when orthognathic surgery is
14 involved. The draft language already includes provisions
15 for orthognathic surgery, which would be these orthodontic
16 cases.

17 As a matter of Blue Cross policy we have not
18 elected to pay for CT scans under the dental policies at
19 this time. Our idea is that, if a scan were to come in, we
20 would look at it on an individual case and perhaps give it
21 an alternate benefit. This is something that we're
22 considering. Scans which are needed for special surgical
23 cases would most likely be covered under the medical plan by
24 an individual consideration review by the medical
25 department. Again, this is not through a dental policy.

1 Important issues with orthodontics that I think
2 need to be addressed is, orthodontia is a dynamic process
3 which the bony structures of the face and jaws are
4 constantly changing during treatment. It is true that
5 comparable images with this new technology will occur to
6 that flat-plane technology and perhaps give you more data.
7 But the movement of teeth contains so many variables that
8 initial sets of x-rays and ongoing sets of x-rays tell you
9 conditions right here, a snapshot. It is up to the skill of
10 practitioner to move those teeth into the proper position.
11 Traditionally initial orthodontic records have been used to
12 develop those bony relationship in order to begin treatment.
13 To that end, a cephalometric film, which is completely
14 different than the panoramic films that we've been
15 discussing in the past meeting and a little bit in this
16 meeting, is important to the orthodontist in designing a
17 treatment plan.

18 In some cases when a dentist, the orthodontist,
19 wants to see with the image, what the patient's outcome
20 would be, there is technology available that is predictive
21 software which you can show what the soft tissue and the
22 teeth are now, plug in a set of variables and get an
23 outcome. Obviously it's not 100 percent true, but it is
24 predictive technology, and it gives you an idea as for your
25 treatment planning.

1 So my issue is, why spend \$500 to take some x-rays
2 when \$200, the typical cost of a cephalometric and a PAN,
3 can give you essentially the same information?

4 Furthermore, at this time many orthodontists still include
5 their records within their total treatment costs. If these
6 orthodontists were doing -- or general practitioners were
7 taking CT scans, would they be willing to absorb the cost
8 into their total fee without raising their total fee?

9 Insurance rarely, if ever, will pick up the entire cost of
10 orthodontics. Even just a few hundred dollars more will
11 create treatment to be more unaffordable for the masses.

12 At the time that I stated that CT scans would be
13 important in orthodontic cases is in orthognathic surgery.
14 Orthognathic surgery is a complex treatment where the jaws
15 are surgically cut and repositioned to a new relationship
16 not achievable with standard braces. It is not commonly
17 performed, and qualified oral surgeons perform this phase of
18 the treatment. Landmarks and 3-D relationship are important
19 here. The surgeons and the orthodontists need to know where
20 the nerves and the sinuses are in order to have successful
21 surgery with the least amount of complications.

22 Another point to note, the American Dental
23 Association publishes standard codes for coding procedures.
24 Recently they have released their 2007 codes. The 2007
25 codes includes CT imaging codes. What the American Dental

1 Association has done, however, was legitimatize the breaking
2 up, the unbundling of the procedure which most people are
3 doing today. They have done -- they have given a code to
4 obtain the image and a code to manipulate the data to see
5 the image.

6 In my mind, working with the insurance company and
7 seeing claims every day, I can see costs increasing just
8 because of the splitting of codes. There are provisions
9 that cover orthodontic CT scans in the draft, orthognathic
10 surgery. We should stay with the draft as it is. A good
11 practitioner of doing orthodontics will be able to
12 anticipate the movement of the teeth. Of course, the CT
13 scan is nice to understand the movement in advance, but
14 you're still going to do the treatment, as my opening
15 statement was. If it's that complicated that you wouldn't
16 do the treatment and you would honestly say "no," then the
17 CT scan is important. I think that the movement of teeth
18 is -- having the scan is not nearly as critical as we
19 decided that knowing where the complex is during the
20 extractions and the placement for bony relationships during
21 implants.

22 I'd just like to address a couple small issues.
23 As an insurer, whether we allow a CT scan at 200, 500, 50,
24 it does matter. Utilization I don't think is totally
25 affected by how many we would regulate. A case in point is

1 there's CAD/CAM technology out there for constructing crowns
2 and onlays and certain procedures like that. That is an
3 unregulated -- there's no -- there's no Certificate of Need
4 on that. We do not see that doctors -- it's \$100,000
5 machine. We do not see that doctors are not utilizing the
6 machine, just only when necessary. We see the doctors
7 utilizing the machine because they feel it is very good for
8 their patients. I'm not going to get into the philosophy
9 here, but I think that you will see the doctors use it more
10 often, the CT scans. They won't just limit it to a few
11 patients when they have it in their office.

12 I was speaking to an implant -- a dental
13 implantologist, even though there's not a real specialty
14 like that, who's been doing implants for 30 years, and he's
15 sent some of his patients for CT scans. However, for the
16 past 30 years he's been successfully placing implants into
17 patients' mouths, and when CT's are -- when the machines are
18 fully certified, he won't use it on every patient. He will
19 say that, "The ones that I really need to see the bony
20 anatomy, I will not use it for. Other patients I do not
21 need it."

22 Kodak has a system where they can do --
23 extrapolate three-dimensional images. Now, I realize that
24 it's probably not as high of a quality as a true CT scan,
25 but it will give you a relationship of extrapolating what a

1 3-D image is. And it's considerably less expensive than the
2 machine. If there's any questions of me, I'll be happy to
3 entertain them at this time. Otherwise. Thank you very
4 much to the Commission. Yes?

5 MS. MOORE: No, I'm --

6 MR. MELENYK: Oh, no questions. Okay.

7 MS. MOORE: Yeah, I am sorry. This is a public
8 hearing, and at public hearings it is only the Department's
9 intention to take public testimony. Questions and answers
10 would be handled at an open commission meeting.

11 MR. MELENYK: Thank you very much.

12 MS. MOORE: Thank you. Is there anybody else that
13 would like to give public comment today? Seeing none, we're
14 going to go ahead and adjourn the hearing at 10 minutes
15 after 11:00. Thank you, everybody, for coming in.

16 (Proceedings concluded at 11:10 a.m.)

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