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CMS REGULATION OF HEALTHCARE SERVICES

THURSDAY, OCTOBER 3, 2002

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The Committee met, pursuant to call, at 2:10 p.m., in Room 2360, Rayburn House Office Building, Hon. Donald A. Manzullo [chair of the Committee] presiding.

Chairman MANZULLO. Good afternoon. We have an interesting scenario going on over on the floor, but what else is new in life? Let me get through the opening statement here and then we will have to adjourn and come back for the remainder of the hearing.

And I thought it would be a good idea, just before the Congress ends to try to tie up as many loose ends as possible. And perhaps Mr. Scully could help us on that.

This hearing really is in three parts. The first part is an update on the administrative process of exactly how to deal with Mary Harroun's combination of a walker and seat known as a Merry Walker.

I am going to be asking Leslie Norwalk to sit at the table and give us an update on the administrative process. Leslie, I know when you were in my office, we asked it be concluded within 60 days. We were subsequently advised that you wanted to do a lot more research and investigation into that.

The second issue deals with the portable x-ray provider reimbursement that apparently has reached a stalemate. We want to get that taken care of have asked a couple of people from CMS staff to join us.

The third issue deals with CLIA, and people from CMS, along with Mr. Scully will help us through it.

The purpose here is to have this as informal as possible, to have an exchange going on among the parties. We are looking towards guidelines and a resolution.

I know with regard to the Merry Walker, I think we had three issues in there, and one or two of them have been resolved, and the third one may or may not be resolved to the likings of my constituent, but at least will be on the road to getting that resolved and to go on to working with Mary on further applications and guidelines for the applications that have already been approved by CMS.

We are also going to be joined later on by Dr. David Weldon, M.D. He has asked to address the Committee and talk briefly about the status of the portable x-ray issue. The fact that the rates

are so low, that the portable x-ray people are going out of business, and CMS is actually paying more to do the same services at a great disadvantage to the seniors who are involved.

And my mother was one of those who had the benefits of using the portable x-ray. And then when that was ended in Rockford, Illinois, because of low reimbursement rates, she had to be carted to the hospital, sat in the emergency room, and 4 hours later carted back to the nursing home, all at a cost of several times more than the portable x-ray. We are quite disappointed that that issue has not been resolved. So that is going to be the purpose of the hearing.

[Mr. Manzullo's statement may be found in the appendix.]

Chairman MANZULLO. And Dr. Christensen, did you have an opening statement?

Mrs. CHRISTIAN-CHRISTENSEN. I do, Mr. Chairman. Did you want me to go ahead and do it now?

Chairman MANZULLO. Did you want to do it now or wait until we get back?

Mrs. CHRISTIAN-CHRISTENSEN. I will wait. I will make an informal statement.

Chairman MANZULLO. As a Member of Congress and also as a medical doctor, I want to give you some time.

Mrs. CHRISTIAN-CHRISTENSEN. Thank you.

Chairman MANZULLO. We are adjourned here for a few minutes.

[Recess.]

Chairman MANZULLO. Dr. Christensen.

Mrs. CHRISTIAN-CHRISTENSEN. Thank you, Mr. Chairman. I want to thank you for having this hearing. I appreciate any time that we have the opportunity to have Mr. Scully with us to address the issues that are affecting our health care providers and the patients that they serve.

I am glad that we are going to revisit the Merry Walker issue again. I think it is a very appropriate example of how the implementation of CMS regulations sometimes just don't serve the patients or the provider well. I hope that we will be able to resolve that issue today.

And beyond that, even make a start at seeing how we can best fix the problem more systematically. I had the great experience of being with my local doctors last weekend as they were meeting with the representatives of our carrier in Puerto Rico, Triple S. I applaud the effort that they are making to try to address the concerns of the physicians, but I really think we still need to fix the contracting system.

Even you, Mr. Scully, said that it was flawed. I don't think we are going to be able to address a lot of the concerns unless that is fixed. So I just wanted to say that on the record again.

As we meet, the issue of restoring cuts to provider payments, has not been resolved. There was an attempt today here. The Senate was to have marked up a bill this week, they have not marked it up yet. And I still hold that CMS can do it administratively. I want to get it on the record. We are forcing providers out of business. In doing so, we are denying many people in this country access to health care.

I also want to underscore that just doing a Medicare give-back bill wouldn't necessarily either get to the heart of the problem. We

really need to look at how the fees are set and what are the parameters used. We said it before that the GDP was not a good way to determine what our Medicare fees should be. The issue, one of the issues I wanted to mention also is HIPPA. As that is looming very imminently ahead, small hospitals and other providers need funding and technical assistance, I think to make the changes that are necessary to become compliant, and I hope that we can begin to identify where such help can be found.

And with the history of audits and the investigations, which I have, at least on two occasions, asked for a moratorium on, it causes us to be concerned over what will happen as these new regulations are put into effect, because we know that the costs of time and money for review or reconsideration process is usually something that most of our small health care providers can't afford. And it turns out that many of those investigations don't find anything except innocent mistakes. So I would like some reassurance from CMS that there will be some flexibility and more help and technical assistance rather than punitive measures imposed as we begin this very complex process.

One more issue I would like to add, and otherwise I will submit my entire opening statement for the record. And this is not in order of importance. I still have a problem with the prescription drug card that the administration is proposing. The card—I think given the fact—it is a poor substitute for a comprehensive Medicare prescription drug benefit. It not only will not provide substantive help to seniors, but it has the potential of hurting our pharmacies and our chain drug stores. This is, I believe, the third reincarnation of the program. I would like to know what is different about this program? How will this program help more than the others? How is it different than it will pass muster with the courts?

With that, I would like to thank all of you who are here to testify this afternoon. Thank you for giving me the opportunity to make an opening statement and welcome again.

Chairman MANZULLO. Thank you, Doctor. What I would like to do is do the testimony in thirds. Mr. Pence do you have an opening statement?

Mr. PENCE. I do very briefly, Mr. Chairman. I want to thank you, Chairman Manzullo, for calling what I think is a very important hearing at a very busy time on the legislative calendar.

As the chairman of the Subcommittee on Regulatory Reform and Oversight of this Committee, I regularly hear from small business people who are struggling under the heavy hand of government regulation. Often it is a small entrepreneur with a new idea for making a product or a family business, like yours, Mr. Chairman, passed down over generations that finds itself unable to stay in business because of the cost and the burden of onerous government regulations.

But I must say, in keeping with today's hearing, I think it is particularly troubling when I hear from physicians in my district, and even in my home town, which is represented here on our panel today. People who oftentimes hold life and death in their hands, the very well being of the citizens that we serve, who tell me that they are unable to give their patients the best care possible, in part because of government regulations.

The Clinical Laboratory Improvement Amendments Act of 1988 or CLIA, is the issue that I have been a part of bringing to the committee's attention today. CLIA, as we all know, is administered primarily by the Centers for Medicare and Medicaid Services. So I am particularly grateful for Administrator Scully's participation today, and wish to thank you publicly for being here.

CLIA's inception was in reaction, we all know, to poorly performed laboratory tests that resulted in missed diagnosis, particularly of cancer. It was absolutely a tragedy. CLIA's aim was to prevent errors in laboratory testing and reporting.

In certain respects, these efforts have been commendable, and in some ways quite successful. The difficulties however, began in treating a single physician the same way we would treat a 1,000-person laboratory. In other areas of government we have been convinced that the one-size-fits-all regulation isn't the answer. In the field of health care, I simply believe the same rule should apply.

The Secretary of HHS, Tommy Thompson's Advisory Committee on Regulatory Reform, has put together some important ideas on changes to CLIA. We hope there are opportunities to work with CMS on other changes and hopefully here some today. I think we will hear in this hearing today, Mr. Chairman, reasons for reform on the burden that physicians face.

And hopefully in this hearing, we will begin to hear the beginnings of some very needful reforms under this new administration. I look forward to hearing from all of our witnesses. I would echo the chairman's appreciation for your willingness to travel here many miles and endure the scrutiny of a Congressional panel.

And again, we thank you, Mr. Chairman, for your leadership in this area.

Chairman MANZULLO. Well, thank you.

I want to do these in triplets, or in three parts, to keep the testimony as tight as possible, and first talk about the issue with the Merry Walker. Mr. Scully, if you wanted to comment on that, or if you wanted to defer to Leslie on that, on the status, however, you know, since you are the lead witness, one of the lead witnesses on it, however you would feel comfortable.

Mr. SCULLY. It depends on what Leslie says.

Chairman MANZULLO. We are looking at the administrative status on that. It is up to you.

Mr. SCULLY. I would be happy to talk about it.

STATEMENT OF THE HON. THOMAS SCULLY, ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES

Mr. SCULLY. If you wouldn't mind first, so I don't forget to just quickly run through the Congresswoman's issues, could I jump to those and then go straight back? Because a lot of them—they are all important issues.

Let me start with the drug card, as you know this is something that came out of our career staff. And I talked to you before about it. We clearly don't look at that as a substitute for a Medicare drug benefit. We really wanted to get a drug benefit this year. We spent a lot of time supporting the House bill.

We showed great willingness to work on any kind of variable with the Senate. And I am personally very disappointed, it doesn't look like we are going to get one this year.

We believe that the drug card, as I said before, I represent 40 million seniors and disabled, we believe they walk into a pharmacy and pay the highest prices. We all have, or I have Blue Cross of Virginia. I probably pay 15 to 20 percent less because of their use of a PBM than a senior does, and we are basically trying to organize the seniors to have the same kind of purchasing power people under 65 have in the interim.

In the long run, seniors want an insurance plan where they are going to pay $10 a prescription like I do. In the short term, we want to give them some hope by coordinating their market power. We have spent a lot of time with the drug makers, the retail pharmacists and the chain drug stores. We understand their concerns. I think the new reg is much tighter, and answered a lot of their concerns. They have not actually sued us yet.

Ms. NORWALK. They filed Friday.

Mr. SCULLY. We spent a lot of time talking to them. I understand their concerns. They have a lot of legitimate concerns. They are concerned that we organize 40 million seniors, and seniors pay the highest cost in a retail pharmacy, they are concerned more that we are going to go to mail order, which I don't think will happen, we are concerned about that.

They are also concerned that if seniors pay lower prices, they are going to get stuck in the squeeze and their margins, where there are high costs on seniors will be lower.

We have every expectation that people under 65 may pay more, but we don't believe people over 65 should be paying the highest prices, which is what happens right now. So that—we are trying to work with the pharmacists as much as we can. The drug card is clearly a short term—I think it is a little more than a band aid, but we believe it is a help. We also think it is a first step.

We have had a lot of bipartisan support. You may have noticed that in the Senate, one of the few things that got through the Senate in the drug bill was that both sides on a bipartisan basis, said the drug discount card is a good idea. But we have never held it out as a substitute or even a short term fix. Almost all of the bills, Democratic and Republican on both sides, envision us organizing 40 million seniors into purchasing co-ops. That is all we are trying to do. We are very sensitive to the pharmacists' concerns. I never expected them to like it, but I do think we have bent over backwards to find ways to address their concerns, purely because of the lawsuit, because there is a question about our existing legal authority or ability and our rules to answer all of their concerns, we are kind of in a catch-22.

The more we tighten up our rule, the more people—there is a legal question about our authority to do it. So, but we are committed to working with them. I spent a lot of time talking to them. I went and spoke at their annual meetings. I have talked to the chain drug stores, and you know we think they have a lot of legislate concerns we would like to address. We also think that we have 40 million seniors that aren't organized, and we have a responsibility to organize them.

I am glad to hear you have a good relationship with your contractor. As you know, we want to do contracting reform. I think there is a pretty good chance, if we do get a bill in the next couple of weeks that we are going to get contracting reform. SSS is part of Empire. My guess is they will probably be involved no matter what. But they tend to be one of our better contractors. We think that we can do a lot to improve that system.

On physician payment reform. Chairman Thomas and many other people hope that I can fix that on my own. I can tell you I have spent many hours with every lawyer in the government. We can't fix it. Unfortunately, there is a negative 4.4 percent update coming on top of last year's negative 5.4 percent, and we are very strongly trying to fix that this year.

And as I think you would ask, I have been the number 1 advocate of fixing it. And the administration does not look at that as a give-back. We look at it as a technical fix. The formula is screwed up, and we are determined to fix that. We are not great fans of a big give-back bill, as you know. But we do believe that Congress absolutely has to fix the physician payment formula before we leave or we are going to have a significant access problem.

So we are completely in support of that. And the two other quick things, I will mention HIPAA. I agree with a lot of your concerns about HIPAA. We have a lot of work to do on HIPAA, but I do think in the long run, all of the doctors' offices, all of the hospitals, and I used to represent 2,000 of them, you know they now get billed by 25 different insurance companies with 25 different sets of forms. It is going to be difficult and intimidating to go to one common set of forms.

It may be difficult a year from now when we flip the switch and use a common data set. But people have been talking about this for 15 years as the right thing to do. I think 2 or 3 years from now when you go into a lot or a physician's office, they are going to have a lot lower need for clerical staff, hopefully, because they will have one set of forms for every insurance company, and for Medicare and for Medicaid. It is an intimidating task, and we are responsible for the education. It is going to be tough.

But I do think that we need, at some point, to close our eyes and take the leap of faith and have every provider use one set of common codes. In the long run, it will do a lot to debureaucratize the billing system. And we are hoping to do the best we can to work with your providers to educate them on that.

The last thing I have tried, maybe I will just use this as my introduction to the other issues we are going to get into. We tried the best we can to debureaucratize CMS in the last year and to deal with people, even this morning at our staff meeting, I was in North Carolina, rural North Carolina touring five hospitals on Friday. I came back and gave the example of one that had a minor investigation 5 years ago. It turned out after 5 years of investigation, that they had no violation, but they spent $1 million dollars on legal fees on a 60-bed hospital. And that is the kind of thing that drives people crazy.

We are doing the best we can to avoid that kind of thing. On the other hand, we are spending $560 billion of taxpayer money every year in Medicare and Medicare and S–CHIP and you have to have

some reasonable guidelines to make sure the programs don't get defrauded.

But I think we have made a lot of gains. We are here to talk about the issues that came up 4 or 5 months ago. And I think we have spent a lot of staff time and made a lot of effort. We haven't resolved all your issues, but we spent a lot of time on them. And I will just jump in by talking about Merry Walker.

If you would like, stop there and go on one by one?

Chairman MANZULLO. Yes.

Mr. SCULLY. On the Merry Walker issue, we almost resolved it during the break on the vote. But we are very sensitive to Mary's concerns. We spent a lot of time on it. Leslie spent a lot of time on it. The bottom line is, it is pretty clear that she obviously come up with a creative product that makes a lot of sense.

I am sure in many cases, her ambulatory device makes a lot of sense and would help in a lot of nursing homes. I spent a lot of yesterday in a nursing home in Arkansas. And there is no question that you can pretty much look at it from the perspective of many seniors, that the device makes a lot of sense.

In my written testimony, we laid out a lot of examples of why we have concerns about the Merry Walker. It is a great product. I think we are making a lot of changes in our regulatory basis to make sure it is not automatically coded as a restraint. In most cases it is not going to be a restraint.

Out of about 3,100 I think cases of restraint—6,100, filed complaints about restraints this year, about 30 of them came from Merry Walker. There is no doubt the company, that Mary had no intention of having it be designed as a restraint, but we have a statutory requirement that if anything, whether it is a wheelchair with a belt, whether it is bed with a brace on it, whether it is a walker that is intended to be helpful for rehab, which this one is; if a patient who is physically or mentally limited has trouble getting out of it by themselves, we have to code it as a restraint.

I think Mary's major concern, and I think we have had some gains with your staff's help in the last few months, is that nursing homes haven't been buying them because they thought they always had to code it as a restraint.

And so if they are going to have to report it as a restraint and fill out pages and pages of forms they weren't going to buy it and use it. We have made a big effort in the last 4 or 5 months. We have sent out a guide to almost every nursing home in the country saying this should not automatically be coded as a restraint. We are about to send out to all of the State surveyors guidance that says that it should not be coded as a restraint.

In talking to Mary during the break, I think she—apparently didn't know it—we are coming up with a new code that takes it out of a category that apparently more automatically throws in that problem area.

But it is clear we spent a lot of time looking, probably more time looking at this device than any device in the world, I would guess the last 6 months. There are some cases where clearly, and yet I think you can see it by looking at it, an elderly patient who maybe much better off in this than a wheelchair, and in some cases, can't

get outside of the railing, and can't get out of the thing, and it is not intended to be used as a restraint, but it might be.

And in these cases where we have tried to set up a situation where if nursing homes essentially certify, they would not be consider it automatically as a restraint, which is Mary's number one concern. But a nursing home would have to say, we don't believe for this patient it is a restraint. But for other patients, there are a subset of patients where it could be a restraint, we have at least 30 examples where patients have had significant problems getting out of it, or have fallen. That is not the intent. Clearly having been in a lot of rehab hospitals over the years, it is a great device, and probably could be very helpful to a lot of patients.

But clearly you can see in some cases could be difficult for some patients to get out of. So that is the problem. Your original request, or Mary's was that we never classify it as a device. I think we have gone to every length—sorry, as a restraint, every length we can to educate the provider that it should not be used as a restraint.

But that they—if they basically find that for that patient it is not a problem, then it is not a restraint. Because the issue for her, if it is ever classified as a restraint in the MDS system, the nursing home then has to fill out lots of forms and must have greater oversight, which is clearly not the case.

And, I think for many patients this is probably a far better device than a wheelchair. That is pretty obvious. I think it is also obvious that for the agency to say this could never be a restraint for any senior in a nursing home also is inaccurate.

So that is—I skipped over my testimony. But that is a quick summary on that subject. We spent a lot of time talking.

[Mr. Scully's statement may be found in the appendix.]

Chairman MANZULLO. I would like to go to Leslie Norwalk, who is the policy director and counselor to the Administrator at CMS. And I just want to take you back to our office. When was that, in June?

Ms. NORWALK. In June.

Chairman MANZULLO. Our goal was to try to get the resolution in 60 days, and that time has come and passed. But, there have been reasons for that, because I know you have been doing a lot of research on it. If you could bring us up to date, give us the legals, where we are exactly on it, and then, Mary may have a question or a comment and we can take it from there.

Ms. NORWALK. As Tom alluded we—Barry and I, actually spent, your fabulous regulatory counsel spent——

Chairman MANZULLO. I will note that for the record.

Mr. PENCE. Move to Strike.

Ms. NORWALK. But of course. We spent a significant amount of time after that meeting, and I think it was July 10th when Barry and I actually came to some understanding that the resident assessment instrument, which is the guidance that goes along with our Minimum Data Set that nursing homes are required to fill out, those instructions to the nursing homes, we altered those and amended those, so it was clear, as Tom mentioned, that it was not always classified or categorized as a restraint and tried to make clear to the nursing homes that they needed to do an individualized

assessment to see whether or not the effect of the particular device had the effect of being a restraint.

And if it did, then they would need to code on the MDS as a restraint. And then, follow the statutory requirements of when it is a restraint. When something is a restraint, the statute requires—that it has to be used to treat medical symptoms, and it cannot be done purely for staff convenience.

And the concern is, that while most of the nursing homes are terrific, but every once in a while you get a bad egg and they might put someone in Merry Walker's fabulous device who wants to get out of it, can't get out of it for whatever reason, and either falls over or they are stuck in here. And Mary totally understands that this should be used, in most instances, with supervision.

Sometimes nursing homes don't have that supervision. So I think—what we did was, we went as far as we could go in terms of making—everything except for saying that it is not classified as—it is never classified as a restraint, but yet trying to be clear that it didn't always have to be one, either, so that middle ground. And we did a lot in terms of educating the nursing homes, getting on calls and talking to the associations, getting this out so that the actual guidance, when someone is looking at, gee, how do I code the restraint in the MDS, they actually read that it is not always a restraint, and they have to do an individual assessment.

So that is where we are. That happened after our meeting. So that is the first step. Now, actually there was a step prior to that. I know that there was a trademark concern that came up probably at the last hearing. I think we did resolve that issue. So those are the two issues in terms of resolution, we have come to resolution in terms of that.

If you think, Mary, after looking at this that you might define something differently, we have put it out in draft form to make sure that nursing homes understand the clarifications. If they don't understand, we will go ahead and revise it.

The third step that we did, or that is in the works, is we are putting out a new version of the MDS. The Secretary 's Advisory Committee on Regulatory Reform that Mr. Pence referred to earlier, we spent a lot of time on that committee as well. So one of things that came up was that the MDS itself was simply too burdensome. So with Tom 's help, we reduced the actual burden on that by 20 to 30 percent, we reduced the questions so the nursing homes would be able to answer it more quickly.

Now, the new version of the MDS should roll out about 2004. And in that new version, the way that we currently code the Merry Walker is in one of five categories. The five categories are bed rails—two different types of bed rails, a trunk restraint, a limb restraint and chair prevents rising.

Now the Merry Walker does not intelligently fall in any of those five categories, admittedly so. So we have put in our new instructions that even though we understand it shouldn't be a chair prevents rising, we would like to code it there until 2004 when we will have a new category. We will probably have an "other" category, because there may be other things that don't fall into those five. And we would like to make it as easy as possible for nursing homes to pick one that is the most appropriate.

That won't happen until 2004. But that is in the works to also be resolved. Of course, if it is not a restraint, you would never code it there. Elsewhere within the MDS, there is a section—it is an ambulatory device, a walker or a cane or a crutch. You may code it in both places.

I think what I—and Mary, you can help me with this. I think where we are now, is that Mary would like us to do something more to get people out of wheelchairs and into the Merry Walker. I think that that might be—there may be some of that that is part of a restraint discussion, but I think the rest of it is really beyond the what is a restraint discussion and something that steps farther, that we haven't really done brain storming on. That is certainly something that we could do with her, without your brilliant regulatory counsel in the room.

But, at this point in time, I think that we have done, about as far as we think we can, given our concerns with the complaints that State surveyors have had as to restraints.

Mr. SCULLY. Talking to Mary during the break, the vote, one of Mary's concerns is, I was at a 95-bed nursing home yesterday in Little Rock. There are a lot of people in wheelchairs that could and should be in a more appropriate device, that they are not going to sit in a wheelchair all day. That may well be correct. And we have a lot of problems with nursing homes, both with payment and level of care and level of staffing.

But I think that goes beyond how we someday incentivize facilities to use better devices, as different than a restraint. You can probably fall out of a wheelchair as well, but the issue is, as a statutory matter, anything that a person cannot get out of easily, has to be classified as a restraint. I think we have gone as far as—very far in clarifying that in most cases, it will be—I think Mary's number 1 problem is it is hard to market it. It is a restraint. We have to fill out lots of paperwork. We have gone to great extents to make it clear to nursing homes and to our contractors and to the State surveyors that unless they say for this patient, it may be a restraint, and won't be classified as such.

Chairman MANZULLO. Okay.

STATEMENT OF MARY HARROUN, M.S., LNHA PRESIDENT, MERRY WALKER CORPORATION

Ms. HARROUN. I am Mary Harroun, the inventor of the Merry Walker. I am a geriatric psychologist, licensed nursing home administrator. I invented the Merry Walker 12 years ago.

I discovered this about a year and a half ago when I was at an Alzheimer's conference and had not kept up with on the MDS because I am not in clinical practice any more. Leslie did give to Barry a copy of all of the deficiencies. I believe we came up with 30 deficiencies on the Merry Walker. I read through them extremely carefully and found out, gleaning through them, that there were 32 documentations required in order to use a Merry Walker in a nursing home if it is considered a restraint.

I talked to a number of nursing homes that had actually used the Merry Walker and were cited as—that it was cited as a restraint when, in fact, they were not using it as a restraining device. I do have some problems with that.

[Ms. Harroun's statement may be found in the appendix.]

Chairman MANZULLO. Let me take you forward. Based upon what Ms. Norwalk said on since the meeting we had in our office in July, okay, would you comment on what she said?

Ms. HARROUN. I have not seen a copy of that, so I cannot—I have no knowledge of that.

Chairman MANZULLO. Is this in draft form?

Mr. SCULLY. She only has one copy.

Ms. HARROUN. No, I did not receive this from you.

Chairman MANZULLO. Our efficient Regulatory Counsel sent it to you.

Ms. HARROUN. I did not receive it. So this is the first time that I have actually seen this.

Chairman MANZULLO. Ms. Norwalk, the purpose of that is to advise nursing home administrators that this is not automatically a restraint?

Ms. NORWALK. That is correct.

Chairman MANZULLO. All right. Mary.

Ms. HARROUN. That would be fine.

Chairman MANZULLO. That was one of your goals in there. Go ahead.

Ms. HARROUN. What we need to do is make sure the resident, of course, is appropriate to use the Merry Walker, which I have always advocated they need the assistance of one.

Chairman MANZULLO. Okay.

Ms. HARROUN. Or stand-by assist, whatever you want to call it.

Chairman MANZULLO. Let me stop you right there at that point. Ms. Norwalk, what Mary said, that this device cannot be used by a senior alone, there has to be some person to assist them. Is that part of your guidance in the letter that went out?

Ms. NORWALK. The guidance that went out purely addresses how it is that a nursing home fill out paperwork. So how it is that they code it, so that we can do a full care plan and assessment. It is part of the care assessment that the nursing home has to do for every single patient.

Chairman MANZULLO. How many pages is this form?

Mr. SCULLY. Well, in fairness because the nursing homes actually look at this, but we went through major nursing home reform a couple of years ago. We now have prospective payment for nursing homes. The way we both track quality, I note that we are going to have a public outcomes rating in every newspaper in the country November 12th of every nursing home, all this comes from the MDS data, but they also get paid on it. So when you are in a nursing home, there is a fairly thorough evaluation that is done on a regular basis to decide how you get paid.

So depending on how sick, how old they are, what complications they have. We pay about $12 billion a year, $13½ billion a year this year in payments for Medicare payments to nursing homes.

It is always done based on the patient evaluation. So the forms that they fill out are not for regulations, they also determine the payment that they get.

Chairman MANZULLO. Okay.

Ms. HARROUN. I have a question. Since I have not been educated in the MDS because I have been out of the clinical area for 12

years. The RUG, is that—those are based on payment. And from what I understand, and please correct me if I'm wrong, if a resident needs higher intervention in care, more nursing, they have decubitus ulcers, they can no longer walk, they are incontinent, they need assistance with ADLs, does the nursing home in fact get paid more money for that resident care or do they get paid——

Mr. SCULLY. Yes. Much like we went to DRG's, which are diagnosis related groups in 1985 for hospitals, and a few years ago went to ambulatory payment codes for outpatients, RUGS are resource utilization groups. There are 88 of them. I may be wrong. And there are 88 categories. As a nursing home patient, they fill out a form about how mobile are you, do you have Alzheimer's? What your various illness problems are. How many activities of daily living do you need help? It is done periodically during the nursing home stay.

And basically that determines what we use to track quality, but it is also used for payment. So if a nursing home identifies the patient as having higher acuity and more illnesses and more trouble with various activities of daily living, they get paid more—there are 45 RUGS payments.

Ms. HARROUN. If I were owner of a nursing home, God forbid, I would not be in there, wouldn't it behoove me to run my residents right on the edge to receive higher payment for Medicare, or poorer care? If I have a resident sitting immobile, either in bed or a wheelchair, and they are probably going to develop a level 1, let's start with a decubitus ulcer, it then goes up to level 4, I would receive more payment for that patient's ulcer than if I kept them ambulatory in the first place and not ever allowed them to have a decubitus ulcer?

Mr. SCULLY. Well, you can say the same thing about any prospective payment system, whether it is hospital inpatient or outpatient. We track them pretty closely. I think we measure quality very closely. I think you are going to see it—I forget where you live, Mary, Chicago. You are going to see a full-page ad in the Chicago Tribune on November 12th, comparing on a number of quality measures, including bed sores, how every nursing home in the Chicago area compares.

So those that aren't doing a good job, may theoretically get paid more for having sicker patients, but you are not going to look very good and you are going to have a hard time the next time a family tries to find a nursing home if you have the worst outcomes in Chicago. You are going to lose business.

So you do, in fact, get paid for higher acuity, but it also shows up in your quality measurements.

Ms. HARROUN. Now, the quality measures I also have a problem with, in that you are measuring in one section of that, under the long-term care section you have acute care and then long-term care. One section is measuring the amount of restraints used in that nursing home.

If, in fact, Merry Walker is being considered a restraint, that will then take away the thrust of wanting to use the Merry Walker, even though—when they have to regard it as a restraint, because that is going to knock them down in the quality measures and show them that they are, in fact, a worse nursing home.

Mr. SCULLY. If they are defined as a restraint, as we said earlier, we have gone to great lengths to make sure nursing homes know if there was a mistaken problem in the past where they thought that they would use a restraint, in the future that is not going to be the case.

One of the measures of quality is number of patients in restraints, because that is one of major patient concerns over the years, is nursing homes that restrain patients for convenience and nothing else. And I think we have made it pretty clear that except for patients where this could be a problem, it is not a restraint.

Chairman MANZULLO. At this point, the Merry Walker is no longer automatically considered a restraint?

Mr. SCULLY. That is right.

Chairman MANZULLO. And then, Mary, would your situation, you are going to have to—I think you are looking at a marketing aspect, as to which HCFA cannot get involved in, because everybody knows it is common knowledge in your statement that the fact that people are better off in the Merry Walker than they are in a wheelchair. Okay.

Ms. Norwalk, at this point then, is there any more that CMS is planning on doing with the Merry Walker besides that advisory that you are putting out to the nursing homes?

Ms. NORWALK. Just when we revise the MDS system when it comes out in 2004, we will have an additional category so that it is put in a more appropriate category than "chair prevents rising", so that it is coded more appropriately, so that people aren't confused as to where it should go.

Because clearly this is not a chair that prevents rising.

Mr. SCULLY. That only kicks in if the nursing home itself determines for that patient it may be a restraint. Our goal here is to make it abundantly clear to every nursing home and every State surveyor for a patient who can, in fact, use this and get out of it themselves, which the vast bulk of patients can, it is not a restraint and they will never even get to the second category.

Chairman MANZULLO. My question would be, when the term Merry Walker it will have the TM on there.

Ms. HARROUN. R.

Chairman MANZULLO. Are your questions answered?

Ms. HARROUN. Yes.

Chairman MANZULLO. Mr. Pence, did you have any question involving the Merry Walker?

Mr. PENCE. No, Mr. Chairman. Thank you.

Chairman MANZULLO. All right. I am going to excuse, Mary Harroun and Leslie Norwalk on this one-third of the hearing. Thank you so much.

Mr. Scully, thank you for the hours you spent. Ms. Norwalk thank you also for the great job you have done on this. I am going to excuse Ms. Norwalk and Mary Harroun. And then let's go on with the testimony. And, Congressman Pence, maybe you would like to introduce your constituents. This is on the CLIA. As soon as you introduce them, then I want to jump back to Mr. Scully if that is okay with you, Mr. Scully, to bring out the CLIA portion of your testimony.

Mr. SCULLY. Sure.

Mr. PENCE. Thank you, Mr. Chairman. Our next witness is a constituent of mine and a friend, and a professional with whom my family has enjoyed a warm relationship for over 25 years.

Dr. Edward Probst hails from Columbus, Indiana. He is the immediate past president of the Indiana State Medical Association. He is a practicing dermatologist in my home town of Columbus, Indiana, and if I may say for the record, is more than any other physician in my home State most responsible for calling the particular changes which CLIA imposed on small practitioners to this Congressman's, attention and therefore to this Committee's attention. It is my privilege to recognize Dr. Edward Probst for an opening statement. And thank you for being here.

Dr. PROBST. Was Mr. Scully going to speak at this point?

Mr. PENCE. I think it was the chairman's intention, from counsel, to recognize Mr. Scully immediately after my introduction, which I didn't previously understand. So Dr. Probst, if you would hold your powder, Mr. Scully, you are recognized.

Mr. SCULLY. I will be quick. I have a long history with CLIA. Just guessing from looking at this thick briefing book that the doctor does as well.

I was involved in the first Bush Administration in the CLIA regulations. They were passed in 1988. There were some changes and the regulations were written when I was overseeing that HHS portion at OMB in 1992.

So I got very involved with those, and a lot of the changes and I followed CLIA pretty closely since. I was also in the interim, when I was expelled from government for 8 years, I was on the board of SmithKline, which is now out of existence, a clinical lab company, their domestic U.S. Advisory board. So I learned a lot about CLIA and clinical lab oversight, some of which has changed in recent years.

So there is no question that CLIA is complex. There is no question that CLIA can sometimes be difficult. But there is also no question that when CLIA was put in, it was because there was a significant problem with quality in clinical labs.

Much of which has improved in the last 10 years, even from our own evaluations in the last couple of years, I can tell you our belief is that the quality of services in clinical labs has improved dramatically.

Congress created a number of different thresholds. Most physician office labs are waived, they are on the waived services, physician lab services are waived from CLIA. That is generally a regular cycle of kind of self-certification. The dermatology issues and others, when you get into higher acuity, higher difficulty types of clinical labs, most of the—that is really when the clinical lab guidance, that is more difficult, kicks in.

In some cases for dermatologist and others for things like melanomas, there is a much more thorough requirement. I am just guessing that the Doctor's concern is, when you get to things like the melanomas or higher-acuity types of lab tests, it is more difficult lab tests.

There are much more thorough requirements from CLIA in the statute. And my guess would be, most physicians would say why do I have to hire a highly-trained clinician or a highly-trained

nurse to do these, I am a doctor I can do these myself. That was a lot of the concern in the late 1980s when this happened is if physicians did it themselves that would be the case. But in most cases it turned up going, for pure volume, it evolved over the years in to nonphysicians doing those labs and doing evaluations, there was a huge level of errors, which is why CLIA was passed for a variety of reasons.

So your concern is, as you state in your opening statement, about a giant lab like SmithKline no longer exists, but there are three or four large clinical lab companies that do the vast bulk of clinical lab services for hospitals and physicians' office should be treated differently from the average physician's office. Generally they are. It is only for the really much more difficult and much more sensitive tests that are done, a lot of them are in dermatologist offices, that the higher threshold for regulatory oversight for CLIA kicks in.

So I would say, I haven't spent as much time as I did 10 years ago, so when you get to the details of this I might even, with the chairman's approval, call upon my staffers who do this every day, to get into the more detailed questions about the regulations.

Chairman MANZULLO. Dr. Probst, you are up.

STATEMENT OF EDWARD L. PROBST, M.D., COLUMBUS, INDIANA

Dr. PROBST. Good afternoon Mr. Chairman, Committee members, thank you for hearing testimony on CLIA, and a special thanks to Representative Pence for responding to my concerns.

I am Edward L. Probst, a dermatologic physician from Columbus, Indiana and immediate past President of the Indiana State Medical Association.

There are many results from the CLIA Act that Congress did not intend. That also have adverse effects on patients, physicians and care. These include physicians no longer offering crucial office testing, physicians limiting tests offered and physicians being overwhelmed by the paperwork of the Act.

I will comment mainly on the latter, but the others are in the written testimony and the attachments.

All physicians want accurate testing. This is not the issue.

The attachment on page 1 is our office calendar of 46 requirement activities in addition to the daily requirements, which are in the attachments, and the additional paperwork for each test done. These binders that I brought show the results of these requirements in our office. Each requirement takes time.

The few tests that I perform relate to the immediate direct care of the patient. Diagnosis of fungus tests, scabies, lice, etc, and are in the area of my training.

Consider the paperwork for a microscopic test done by me in my office while the patient remains in the exam room waiting for the results.

Before CLIA, I would examine the patient, take a scraping, label the slide, carry the slide myself to the microscope, read the slide, return to the patient, record the results in the patient's chart, in red, so we would know it is a laboratory test, explain the results to the patient and outline the treatment recommendations.

What more could be required that would improve this service or the efficiency of its delivery? This was pre-CLIA.

After CLIA—Note the CLIA laboratory requisition form which is on page 31 of the attachments requiring 14 entries, all of which are already in the chart. This is a requisition from me to me. It is a requisition to the laboratory, and that is still me. So it is a requisition from me to me required by the CLIA inspector.

On page 32 of the attachment is the CLIA laboratory test requisition and report log, which is required to be at the microscope, with 10 entries that are already in the chart, and also on the requisition form.

Then, I have to record my findings on each of those forms. Then I go to the exam room and record it in the patients record, which is where I think it belongs in the first place. What added value is this redundant and time consuming paperwork? In my opinion, none.

Time for extra paperwork removes time from patient care. But, in addition to that, each of those pieces of paper has to be reviewed by a quality assurance person to be sure that the data is correct, which can only be correct if it were taken from the chart in the first place, because that is where the data originated. This must also be approved by the laboratory director, who must be a M.D., who would rather be seeing patients.

And then, the M.D. laboratory director must create a summary that gets placed in the CLIA book. All of this is for the CLIA inspector. All of this is time away from the patients.

Let me share two examples about time. Mrs. X, an older lady usually with multiple complaint was in my office. She did not require microscopic testing, and most people don't. After evaluating and giving recommendations, I had time to ask her "Is there anything else you would like to talk about?"

She said, "yes, I plan to kill myself today." She was not kidding. I was the only person she was willing to tell that to. If I had been burdened with a lab test requisition, I might not have had time for concern, and Mrs. X would have died that day.

Mr. Nathan S, and he said I can use his name, a farmer, was in my office for a skin cancer follow. No laboratory test was needed. I had time to inquire about him and his family as we finished. He said "no problems." His wife, Joanne, said, "Nate can't see well today."

He had an acute vessel occlusion. I made arrangements for immediate intervention, and his vision was spared. And it would have been lost otherwise. Time for needy patience, versus time for needless reduplicating paper. That is the question.

The CLIA regulations prevent us from being the caring, compassionate physicians that we are. Please, remove the unnecessary red tape of CLIA, OSHA, HIPA, Medicare, et cetera, so we can do what we have been called to do, be caring, compassionate physicians.

Thank you all for caring. I welcome any questions on my written or verbal testimony.

Chairman MANZULLO. Thank you, Doctor.

[Dr. Probst's statement may be found in the appendix.]

Chairman MANZULLO. Congressman Pence, did you want to introduce Dr. Davey?

Mr. PENCE. Yes, Mr. Chairman.

The Committee will now hear from the Dr. Patrick Davey. He is also a dermatologist with a practice in Lexington, Kentucky. Currently serves as chairman of the American Academy of Dermatology's Association Quality of Care Task Force.

He is a distinguished physician, well qualified to speak to the practical implications of the issues we are addressing today. Dr. Davey is an assistant clinical professor as well as of dermatology at the University of Kentucky. Where, in addition to top flight health care, I understand that they have a basketball program, although I have no proof of that.

Dr. DAVEY. Well, Indiana used to have a basketball program.

Mr. PENCE. I left that one open, Mr. Chairman. And I yield back to the chairman.

Chairman MANZULLO. We look forward to your testimony. The goofy-looking clock is not part of CLIA. It is part of our time system here. When it gets to yellow, that means you have 1 minute. When it gets to red, that means you have no time left.

Dr. DAVEY. I assumed that it was part of HIPAA.

Chairman MANZULLO. Isn't Indiana red also?

STATEMENT OF PATRICK DAVEY, M.D., LEXINGTON, KENTUCKY FOR THE AMERICAN ACADEMY OF DERMATOLOGY

Dr. DAVEY. Good afternoon, Mr. Chairman and Committee members. I want to thank you for inviting me to discuss CLIA for dermatologists and give you a national perspective on the issue, because I travel around the country a lot, and look at individual practices as part of what I do.

I am a practicing dermatologist in Lexington, Kentucky. And in my practice, we have a nine-physician practice. We have a high complexity lab under the CLIA regulations which performs about 15,000 biopsies a year, about 2,000 frozen section margins a year. So it is a little bit different than the perspective that we just got.

So what I am going to tell you is what I see when I go around the country and look at dermatologists' offices. I am also the chairman of the American Academy of Dermatology's Quality of Care Task Force, and deal with this issue on a weekly basis, where we see mostly people who are confused about what goes under the CLIA regulations and what doesn't go under the CLIA regulations.

And finally, the other thing I do is I survey organizations for the Accreditation Association for Ambulatory Health Care, and I also teach new surveyors, so I am well aware of going in and doing surveys and accrediting facilities.

I have a long-standing personal interest in quality improvement and management, and most of the papers that I have written, and also the talks that I give, deal with, how do you set up a quality improvement program in your office. In order to try to bring dermatologists up to speed on this issue.

Most dermatologists are actually in a solo or small practice, about 46 percent. I am the exception in being in a large practice. The CLIA Act, of course, was passed in 1988, and was really a reaction to larger laboratories where there was a problem with pap smear testing, as Mr. Scully alluded to earlier.

And the American Academy of Dermatology initially opposed the CLIA Act, and we advocated passage of legislation to exempt the physician office laboratories from CLIA. And really, since these exemptions, this has really failed. What we would like to do is to have some regulatory relief from the CLIA regulations.

Now, what this really does, what CLIA is really doing is, it is impeding the ability of dermatologists to provide these services in their office to the patients as we heard from my colleague here. That is a problem.

Most dermatologist's office really have limited resource for the CLIA compliance. They don't have the staff to be able to jump through all of those hoops that we are required to do with the CLIA, and we really are very patient oriented, we really want to spend our time with patients rather than spend our time trying to meet the regulatory requirements. The American Academy of Dermatology in 1993 developed a CLIA manual which I have here to show you. It is there for our members. Every time I lift this thing I get a hernia. You can see it is a fill-in-the-blank type of manual so that people can meet the CLIA regulations by filling in a blank.

Since it has been passed, about 75 percent of dermatologists have stopped doing these tests in their office when you will look at our surveys. We are trained to do the tests in our training programs. It is something we are very good at, but it is something that we just can't do because of the CLIA regulations. We can't afford the cost and we can't afford the paperwork that has happened because of CLIA.

What we would like to see happen is that some of these basic dermatologic tests moved from a medium complexity level down to a waived or a physician performed type of testing. And we feel that this could be done without really endangering the quality of care. If you look, for example, the fungal culture that we saw here, that is a very simply test to perform.

You go ahead and do a scraping on a patient, or you do clipping from toenails, you put it in there and you look at it. It is a color change that is going to happen. So you can do it is very easily to see if it is positive or negative based on that color change. It is also something that we had to learn for our board certification. We did that every day in our residency programs and for our board certifications, so we are very well aware of these types of tests.

In my statement, I gave a number of other tests that we would like to see moved from these medium complexity down to a lower complexity.

And hopefully, that is one of things that this Committee will be able to do for us. We would also like to have the Committee weigh in in support of Secretary Thompson's Regulatory Reform Committee. We talked about that a little bit earlier. What this will do, it will give us this information from CLIA in plain English, and we do speak English in Kentucky.

It also would increase the involvement of physicians in these regulations. That is one of the reasons I am here, because I am interested in the process, I wanted to be involved in it. And it would improve really the providers and also the people that are going to be going out and doing the inspections. It would improve their education with respect to CLIA.

So that is why I am here. I would like to have the Committee look at giving us regulatory relief. Thank you very much for your time, and I would be pleased to answer any questions.

[Dr. Davey's statement may be found in the appendix.]

Chairman MANZULLO. Thank you. Mr. Scully, you have a member from CMS at the table.

Mr. SCULLY. Yes, Mr. Chairman. Judy Yost is the director of the CLIA division and certification.

Chairman MANZULLO. What I would like to do is to give your response, or Mrs. Yost's response, I guess, to the problems and/or suggestions of each of the physicians.

Mr. SCULLY. If you don't mind I will give mine quickly, and then let Judy answer appropriate questions. Certainly they raised some reasonable concerns. The Secretary's Regulatory Relief Task Force, I think most of the staff from the organization has come from CMS. We are trying to simplify CLIA.

We are trying to come up with clear education. We would be happy to get the doctor more involved, both of them much more involved. I think, for the most part, a lot of—I think in talking to Judy here, probably the biggest problem we have had is with dermatologists. Maybe we should spend more time with dermatologist trying to find out the deal with their specific problems, because the other major group that I think encounters CLIA the most, the pathologists, are generally pretty supportive and have been happy with the changes we have made.

So maybe we haven't spent enough time focusing on the specific issues with dermatologists, because most dermatologists, from what Judy has told me, and from other places today, dermatologists tend to do the more complex treatments, complex tests to get them under the scrutiny of more CLIA oversight, and they tend to fall into that category more than other doctors seeing patients on a regular physician practice.

Pathologists generally don't have that type of practice. So part of this may be specific to dermatologists, and there maybe other practice groups who have had problems with CLIA, but they seem to have specific and somewhat unique problems with CLIA. I am totally committed to spending more time to deal with some of unique challenges that we present for dermatologists.

Ms. YOST. Just briefly. Thank you. I don't think——

Chairman MANZULLO. What is your position at CMS?

Ms. YOST. I am director of the division of laboratory services at CMS. But just to echo Tom Scully's comments, I also want to say that we very much want to work with the dermatologists, because their issues are important. They are serious. They are unique.

Chairman MANZULLO. Let me stop you at that point right there. Drs. Davey and Probst, have you had a relationship with, or the Academy had a relationship with CMS, it is not as tight as you would like it? Give us some concrete suggestions here so we can be able to follow the thread here on the suggestions. What would you like to see done?

Dr. DAVEY. When you look at our practice, it really runs the gamut. We certainly have things that should fall under the high complexity, like biopsies, skin biopsies. My office, we—if you came into my office, we would biopsy you, and then we would process

that, and we have our own dermatopathologists that would look at it under a microscope.

My lab would meet the CAP, College of American Pathology standards in terms of what we are shooting for in that office. If you have a solo physician that is doing a scraping like this that is going to be scraping——

Chairman MANZULLO. Is that where the problem is?

Dr. DAVEY. We have some tests that we feel should not be at the level of complexity that they are at.

Chairman MANZULLO. Ms. Yost, your comment on that?

Ms. YOST. Just I agree partly with the comment about the pathology. In regard to the—like the KOH and the fungus test from the DTM and so forth that are routinely done by dermatologists we—these tests were actually taken to the Clinical Laboratory Improvement Advisory Committee, which is a technical secretary's advisory committee to the CLIA program, it is an ongoing program.

Chairman MANZULLO. Do physicians sit on it? Dermatologists sit on that?

Ms. YOST. There is not a dermatologist, but there are physicians represented on the committee as well as obviously laboratory experts and consumers.

Chairman MANZULLO. So there is no dermatologist on CLIA?

How many physicians sit on that committee?

Ms. YOST. Well——

Chairman MANZULLO. How many people?

Ms. YOST. There are about 20 people on the committee. And probably 4 or 5 of them are physicians or Ph.Ds.—and the rest are probably Ph.Ds in laboratory science.

Chairman MANZULLO. Do you think it would help you if a dermatologist sat on that committee?

Ms. YOST. They are certainly welcome to be invited to the committee. Obviously it is one of those cases where you have to have a balance between all areas of expertise.

Chairman MANZULLO. I think it is obvious here that they are not represented at all. There is agreement that they should be.

Mr. Scully, what would be the process to appoint somebody?

Mr. SCULLY. I don't know. But I assume I can probably take care of it.

Chairman MANZULLO. Could you do that? Do you understand what he is offering here?

Dr. DAVEY. I am very happy that he has offered that.

Chairman MANZULLO. You bet. All right. So—I didn't mean to interrupt you on it.

Mr. SCULLY. My guess is that technically the Secretary, a lot of these, we have many advisory committees. The Secretary appoints them.

I am sure I could talk to the Secretary, unless there is a statutory limit, if there is, when the next person comes off, we would be happy to appoint a dermatologist.

Chairman MANZULLO. There you are.

Dr. DAVEY. Thank you.

Ms. YOST. Just to let you know, that the issues have been brought up before to the CLIA committee over the years, because of the concerns that have been expressed today, some of the same.

And it was the committee's opinion on several occasions, not just one time, that these tests still were of a complexity because of the complexity, the training and the quality control needed to do these particular tests, that they could not—the type of complexity that they were categorized in under CLIA could really not be reduced. Those things that could be have already been done like the KOH prep. That is being done for fungal elements. So it has been done. That doesn't mean that we can't evaluate that again, and obviously if there is a representative member on the CLIA, then obviously various arguments can be made.

But there was a lot of testimony presented to that group, just so that you know that we have not ignored the whole issue over time. I think this is important to know.

In regard to the very simple tests that you are doing, the more simple tests that you are doing outside of the tissues, I believe that we could probably work with you to reduce your paperwork. We really don't prescribe that you have special forms to order tests, or to report results or to keep a log. You do need to document if you do quality control. But you can actually use the patient's chart to order the test, and to report the result. You don't need to have a separate piece of paper to do that. We have no requirements for that.

So we will work with you to try and simplify that process. I will contact our State folks and get back with you. We would very much like to help you, because you don't need to have those stacks of paper to do those routine types of tests, because you do them every day.

You do need to do, periodically you need to check, a couple of times a year, to make sure that the test is working and document that. But you certainly don't have to have ongoing paperwork on a daily basis for each patient.

Mr. SCULLY. We would be happy to work to simplify this, in many areas of CMS and OSHA, which applies to them in many cases too, regulation. Sometimes the regulations we put out are significantly enhanced by consultants who make people generate 50 times as much paperwork as they need.

So we will do our best to clarify it and make sure that we put the minimum demands on them.

Dr. DAVEY. Mr. Chairman, one of the other problems that we have is that there is not only CMS, there is two other Federal agencies involved in this, in the CLIA Act also. It is one of those cases where we get some piece of information from one part of that Federal agency, and another piece of information somewhere else.

Chairman MANZULLO. Does that Committee try to coordinate, Ms. Yost, does that Committee try to coordinate CLIA with the other two agencies?

Ms. YOST. Yes. All three agencies are represented. I, too, am on that committee as well.

Chairman MANZULLO. Okay.

Dr. DAVEY. There is also a problem with interpretation of the regulations, which I understand completely, because tomorrow I am going to Greenville, South Carolina, to interpret regulations in an office.

Mrs. CHRISTIAN-CHRISTENSEN. I was looking at the faces of the doctors. And, Dr. Probst, you seemed to be surprised to find out that you didn't have to do all of that paperwork. So who is it that regulates that where you are?

Dr. PROBST. The CLIA inspector said we must do it, these are the forms that we must use. We had no choice in that. It was not flexible. And when I persisted and ask why is this any better than what I am doing, I was told we need this so the inspector will have the information.

We were given no choice. And this has been year after year after year. I am glad to hear that it doesn't have to be that way. But how does that funnel down to us?

Mrs. CHRISTIAN-CHRISTENSEN. This is the problem that I found with the carriers. I don't know if the carrier has a role in setting those regulations in this particular instance. But they are interpreted differently. That has to be fixed. Because we have doctors that have moved from one area to the other. And they are just, you know, confounded by the—the difference in how the interpretations are done, and therefore, what they are required to do. It needs to be clear.

Mr. SCULLY. These are slightly different. One is the surveyors generally, you can correct me if I am wrong, but for hospitals, nursing homes, home health agencies, and I am sure for CLIA, tend to be done, we pay for them and the surveys are done by State surveyors under contract to us.

I can tell you that there are standards, paperwork requirements on how they interpret our guidelines do vary significantly State to State, and we can sometimes clarify. But the State is essentially our contractor, so it is an Indiana State employee, working essentially under contract to both the State of Indiana and Medicare, Medicaid for both. And they do the surveys under contract for us.

On the carrier side, we discussed briefly before, we have 51 carriers, FIs, for part A and part B. We are trying to get that down to about 20 to 25.

Mrs. CHRISTIAN-CHRISTENSEN. What can you do to make it uniform?

Mr. SCULLY. To be fair, we are trying to make it more uniform. We just went through this with outpatient drugs where different parts cover and pay for things. We want to make it more uniform, but when it is too uniform then you get complaints that you are not sensitive to the practice patterns in Indiana versus Seattle. The carriers do have some flexibility and I think should, to either cover and pay for, reimburse or allow differences between Indianapolis and Seattle.

On the other hand, we need to have a lot more consistency. I am trying. We have medical directors in each one of these plans. We now have monthly meetings with them. We try to get them to have more consistency.

But we try to find the right level of Federal mandate to say you are consistent and also leave different practice patterns to physicians and hospitals that have different practice patterns in different regions. But nobody is ever happy. But we are trying to do the best that we can.

Ms. YOST. As part of the regulatory reform issue, since that was brought up earlier, I wanted to mention also we are in the throes of publishing final CLIA regulations, which actually are more balanced and more fair than the ones that we have now.

But, as part of that, we are going to be doing extensive training and education of not only the laboratories but our surveyors as well. So I understand your concern. And we will certainly continue to work to kind of mediate that a little bit.

You also have to be aware that some States have their own laboratory licensure programs which may be more stringent than CLIA, in which case we can't interfere with that.

Chairman MANZULLO. Mr. Pence.

Mr. PENCE. Thank you, Mr. Chairman. I have only been in Congress for 21 months. And I have probably found this hearing more fascinating than any hearing I have been involved in since being in Congress, which is not saying much.

But, this has really been fascinating. I can't help but feel that we have opened some lines of communication here that are very valuable and very helpful.

That being said, in your written testimony, Mr. Scully, you pointed out that you have worked hard to streamline procedures, improve flexibility, all of things we have been talking about in an ad hoc way today, reducing the burdens.

You also wrote that we are working to take into consideration the tremendous amounts of feedback we have received on the 1992 rule, so that we can publish a streamlined final rule in the near future, the focus being especially helpful for small business labs that many Medicare beneficiaries rely on.

I think it is very helpful that the Chairman, in his style, kind of getting to a core issue here. Obviously there is, it seems as though the panel lacks an important perspective, from the dermatology profession, and would add my urgent encouragement that a seat be found very quickly for this particular part of the medical profession, that as you point out, Mr. Scully, seems most beleaguered by CLIA in your experience.

But, I wanted to give you an opportunity also to speak, to elaborate on your written remarks. What is the status of that streamlined final rule? What might be the time line for that? And is there still time for, whether it is one of our two witnesses today or someone else representing dermatology, to participate in helping to develop that new streamlined final rule?

Mr. SCULLY. I believe I shouldn't put this heat on my former agency, OMB, but I signed the final rule I think last week. It is in the process of going through the administration. I don't think it is particularly controversial. Well, maybe it is, I don't know. But I haven't had a fight with anybody about it so far. I think it is probably going to be pretty well received and was strongly supported by most of clinical lab groups. The pathologists, I didn't personally talk to the dermatologists. But if there are subsequent problems, we are happy to go back. This is a fairly major rule. But we can go back, we have—it is a huge agency, my budget is about $560 billion.

We have many rules going through. We can make technical changes in lots of areas when we need to do it. So if there are other

things to do it, that make sense we will do it. But the rule, I believe, should be out in next couple of weeks in final.

Mr. PENCE. We will look forward to going over that and getting feedback from not only our witnesses but other folks affected by it.

I guess my last comment is more of an encouragement. I will yield back to the chairman that I think the—and I am not speaking on behalf of the witnesses, but I think that the attitude that you reflected, Mr. Scully, and Ms. Yost, is very admirable and very much appreciated.

Although I will comment that from my vantage point, our witnesses were reacting with, if I can say a degree of incredulity, as Mrs. Yost described what actually was required and what is not required. It suggests to me that not only are we dealing with the fact that there are other arms of the government involved at the table here, but that I—it seems to me, and we are still early in an administration, but I guess I would encourage Ms. Cost and others charged in administering the CLIA law to—I am picking up a philosophy here that is one that as you make other comments of trying to accommodate small operators and create rules that make sense, and allow people to use existing systems, it is entirely possible that there may be a philosophy in the Washington CLIA shop that has not yet invaded the culture of the State offices.

I guess, that is what I would like to most encourage you to do, not just in Kentucky and Indiana, but to communicate to the State offices, what may, in fact, and probably is, in fact, a different governing philosophy that should animate at the State operations that administer CLIA. And I would encourage that.

Mr. SCULLY. One of the problems which having such a program of Medicare and Medicaid is that things fall through the cracks. When I first took the job last year, I met with the heads of all of major clinical lab companies in New York for an emergency meeting for a rule they really wanted out. And they met with me and they told me this rule had been sitting around for 3 years. And their argument sounded reasonable. I went back to Washington and said, what is the deal with this reg?

And everybody said, well, nothing. I said, well, nobody—it had been sitting around for 2 years and hadn't gone out. So sometimes there is a lack of communication. We put that rule out last year, and it was very helpful to clinical labs. For some reason, in the Medicare program, clinical labs is a very small piece.

And to Judy's credit, this probably doesn't get as much attention from me or other people who are administrators. And so it is good to have these focused on occasionally where we are missing things to get these issues raised up and we can cut through them.

But we are clearly committed to doing that. And when you see the final CLIA rule that comes out, it will be helpful. If it is not, we will go back to work and try to make it better.

Chairman MANZULLO. Thank you. We appreciate that, Dr. Probst and Dr. Davey. And did you want to say something?

Dr. PROBST. If I may, sir. I am here as the past president of Indiana State Medical Association representing all physicians. I happen to be a dermatologist, and I think because of that, the response was that only dermatologists have problems with CLAI. This is not true in Indiana.

My testimony related only to requisition because I only had a short time. My written comments and attachments reflect that all physicians have problems. Wet mounts, microscopic urinalysis, various stains for bacteria, the whiff test for bacterial vaginosis, are several tests mentioned by physicians who have added their letters to my testimony.

I am not coming from a dermatologic position. Indiana physicians in all practices are not doing tests that should be done in the office to better serve patients and save them time and inconvenience.

I am not reflecting the position of dermatologists. I am reflecting the position of all physicians in Indiana and the patients there who are not allowed to have the tests in the office, for tests that are best done there.

Thank you for allowing the additional comments.

Chairman MANZULLO. The record will note that. Okay.

Dr. Davey, Dr. Probst, and Mrs. Yost, you are excused. Thank you for your testimony.

Then I would like to have Mr. Tim Tryslit, and Mr. Terry Kay have a seat. Well, we are two for two.

This third issue here has been with us for some time. Several months ago when we had a hearing involving the portable x-ray providers, Mr. Scully at that time said that he would like to have this matter resolved within 90 days.

There have been a lot of discussions going on with the industry. But I would—before I turn this over to Dr. Weldon who has got some base questions to ask with regard to the portable x-rays, Mr. Tryslit, could you please, spell your last name, for the record and give your position.

STATEMENT OF TIM TRYSLA, POLICY ADVISOR, OFFICE OF THE ADMINISTRATOR

Mr. TRYSLA. T-R-Y-S-L-A. I am a policy advisor, like Leslie, in the office of the administrator.

Chairman MANZULLO. And Mr. Kay.

STATEMENT OF TERRY KAY, DIRECTOR, DIVISION OF PRACTITIONER SERVICES

Mr. KAY. K-A-Y. I am a director of the Division of Practitioner Services.

Chairman MANZULLO. Okay. Dr. Weldon.

Dr. WELDON. Mr. Chairman, I want to again thank you for indulging me and giving me the opportunity to be here. I certainly want to also extend my thanks to the ranking member in supporting me, having the opportunity to be here, joining with the panel in asking questions.

And I certainly appreciate the hard work of the President of the United States and Secretary Thompson and Mr. Scully in terms of doing everything that they can to make sure that America's seniors get quality health care.

Before I get onto the portable x-ray issue, which I had some questions about, I just want to say as a clinician, I still see patients once a month at the Veterans Clinic in my district, to bring the tried and true bedside diagnostic techniques of doing scrapings of fungal lesions of scabies and lice lesions.

Every doctor has a microscope in their office. To try to bring all of that stuff under the regulatory burden of a bureaucracy to me is absolutely insane. Any physician who is licensed and accredited to practice in their given specialty, in my opinion they shouldn't have to justify it to a bureaucracy that they are doing it correctly.

But, moving on to the issue of the portable x-ray. As you know I have mentioned this previously at the previous hearing, that, I practiced internal medicine for 15 years before I was elected to the House. I was one of a small group of physicians in the community of Melbourne, Florida, that continued to track their patients once they were admitted to a nursing home.

And I found the use of portable x-ray to be a tremendous time saver, a cost saver and a suffering saver in that patients would fall, patients would have a cough, I would be concerned about a fracture, I would be concerned about pneumonia. Rather than transporting them to my office and having them to go through that ordeal in an ambulance; or worse, having to transport them to the emergency room with a tremendously increased burden of cost associated with that, I found the portable x-ray to be, I thought, just a win-win all around, good for the patients, good for me.

The quality of the response I would get from the portable x-ray providers was superior to what I got at the hospital, and compared very nicely to what I had—we had a large medical group, so we had radiologist rights in the building we were in. So if I brought the patient to my office, I could get an x-ray report over the phone from the radiologist in my building.

But if I brought the patient to the emergency room, it was hours and hours. And frequently I would have to go down to the hospital radiology department and thumb through x-rays to find the x-ray on my patient, whereas with the portable x-ray at the nursing home, I got a phone call from the radiologist.

But, I have some concern about the set-up code. It is my understanding that the set up code which is the Q code for the portable x-ray industry, was established in 1992. And the law required that the set up code be reviewed every 5 years. And according to what I have been told, under the previous administration, and so far under this administration there has not been a review. There has not been a review in 10 years. And the requirements of the law have not been fulfilled.

Is that correct? Has there been a review of the set-up code, cost and reimbursement?

Mr. SCULLY. Maybe I will ask Terry to answer that.

Mr. KAY. All right. At this point it has not. We have been working over the last—since the last hearing with representatives from the portable x-ray industry to, you know, get this review. Kind of in a nutshell, the way our review works is that we work with an outside sort of privately established Committee, which has been formed by the American Medical Association, of about 30 specialty groups and some others, some nonphysician groups, and they review requests.

You know, they look at what staff is needed to do a service, what equipment, what supplies and sort of what resources are required to do these services.

Mr. WELDON. So it has not been done?

Mr. SCULLY. Because I am sure you know, Congressman, Dr. Weldon, we have about $66 billion of physician payments we make every year for physician and related services. And every year we go through the resource utilization committee, to figure out how these codes move around.

As we have tried to explain, the portable x-ray providers get paid from that pot. So we have, in fact, if the new physician fee schedule, which is something we didn't mention, their rate, is in direct response to your interest, they, in their new fee schedule, the draft anyway which is going to go final for January 1st, they are the single biggest increase in the pot. Their rates go up about 8 percent before you do the pro rata cut that we have been talking about.

Dr. WELDON. The physician reimbursement?

Mr. SCULLY. For the overall portion of the portable x-ray supplier, I believe is the largest percent increase in the physician pot, it is about 8 percent. But the underlying expense code of that, which is the part that is just the set-up fee, which is about $11 or something, the idea when they bring the machine up to the nursing home, they bring it inside to set it up, they get paid roughly $30 for the x-ray, varies by area, but roughly $100 for transporting the x-ray machine, and then the set-up fee, which is about $11.

That particular subcomponent, what they get paid for, is reviewed under a practice expense advisory committee. So we have reviewed the rate and changed the rate for next year, as a direct result of your input.

But the set up fee, the $11 out of the $150, is still under review.

Dr. WELDON. I was told that the it was under review and that it was had been determined to be appropriate. Is that true?

Mr. KAY. No.

Chairman MANZULLO. Doctor, would you yield a second?

Dr. WELDON. You are the chairman. I yield.

Chairman MANZULLO. Is anybody here from the industry that would like to put some input into the statements that were just made by CMS? Any correction or anything?

Mr. HALSEY. This just came up yesterday. I am Steven Halsey representing the National Association of Portable X-ray Providers.

Chairman MANZULLO. Do you want to have a seat here? It is up to you. If you want to refute something that was said or add to it, or perhaps Mr. Kay was in the process of saying something and I cut him off.

Mr. HALSEY. It is not a prepared statement. I think that there is some clarity issues that are important, if I can make a brief statement.

We have been working with the people at the table, and I want to say for the record that since your last hearing in May, Mr. Chairman, which I think brought about the meetings that we have undertaken, meetings face to face, conference calls, and individual telephone conversations, I do want to state that on behalf of Mr. Scully and Mr. Tryslit and Mr. Kay, they have worked in good faith to try and get a clearer understanding of the problems in the industry, and how we might go about positively affecting what is simply a disastrous spiral in in the bottom line of the companies.

So while I don't think it is appropriate, or not at this time with the preparation that I have, to talk about some of the very specific

items such as the Q code, the review to our understanding, it has not been reviewed, it is required by law.

But, I do want to state that these people have been working for a number of months in good faith on this issue. But, the reality is, we have absolutely zero effect after 5 months.

And I know for a fact that during these 5 months, there are a number of companies who have gone out of business. There are more that are going out of business. There was a witness who testified before this Committee in May. I spoke to him yesterday, he is laying two people off tomorrow.

Chairman MANZULLO. We are also joined by?

STATEMENT OF NANCY TAYLOR, OUTSIDE COUNSEL TO THE NATIONAL ASSOCIATION FOR THE SUPPORT OF LONG TERM CARE

Ms. TAYLOR. Nancy Taylor. T-A-Y-L-O-R.

Chairman MANZULLO. What is your position?

Ms. TAYLOR. I am outside counsel to the National Association for the Support of Long Term Care, which also represents many portable x-ray providers.

Chairman MANZULLO. Did you have a comment on the statement that some of the CMS people made?

Ms. TAYLOR. Yes. We have a letter for the Committee as well, which recognizes that this is a complex issue, and the National Association for Portable X-ray has done a great job. We have worked with them at CMS.

There two parts of the code that provides transportation money to portable x-ray providers. One is the transportation code, we have been working very closely with CMS to update the fee. The second part, which is the set-up code, requires providers to get adjustments from the Physician Advisory Coding Committee. We could not get on the schedule to seek air increase for September. We have now asked that we be on the schedule in January.

I wish that the CMS administrator could do something about that but he can't.

Dr. WELDON. Well, if I can reclaim my time, Mr. Chairman. That was actually the question I was leading up to, to Mr. Scully. Can you have the Physician Advisory Committee put the set-up fee on their agenda when they meet again?

Mr. TRYSLA. Congressman, we have actually have that feed up for January. They have asked us to look at our top priority of codes, and this is going to be one of those priorities.

Mr. SCULLY. As you can tell, I actually don't do any work myself. I am just the front man.

Mr. KAY. Could I just elaborate on that? The Practice Expense Advisory Committee that we have been working with has been very busy over the last few years revising all of the services and the fee schedules. There are over 7,000 services that we pay. This year alone, we just reviewed 1,100. They, in the last meeting that occurred in September, said that they would, you know, look at the next 50 that we asked them to do.

So, Mr. Scully, you know, certainly has the authority at this point, you know to put this on the top list of priorities for review. So it is a private, independent group. But, they——

Mr. SCULLY. The way it works, Doctor, as you probably know, is they—a lot of these committees, we basically take all of the affected parties, put them in a room. And if we are going to increase payments for portable x-ray, then theoretically it comes out of the pot of somebody else.

So all of the providers get in the room and we discuss and debate what the relative priority of various payments for physicians, labs, other things are. And usually in 95 percent of the cases we take those recommendations. But they are in fact recommendations to me and the secretary, and we can change them if we like, and we do occasionally.

But we would be happy to put this on the top of the list, and I will certainly do so.

Dr. WELDON. I appreciate the dilemma that you face. My primary concern, just so you understand, is if this industry goes away, you are going to pay more money. And your quality of service is going to be worse.

You may not be able to tell that is happening, because the figures are so gigantic. If emergency room services are $20 billions next year, to pick a figure out of thin air, if they are $20.02 billion, you are not going to notice that that increase is due to the fact that you put a much smaller industry that was costing you less out of business.

And the concern I have, just so you understand, is just what this gentleman was talking about. I have got portable x-ray providers telling me that based on the reimbursement schedule, they are not going to be able to stay in the business. And my perspective as a clinician utilizing the service, was that it was very, very good for seniors, and it was good for clinicians, and it was also good for you, in terms of providing better quality at reduced costs.

Let me just get back to the issue. I just want to make sure that I understand this correctly. You have not determined that the set-up fee at this point is adequate? You do not have a position on that?

Mr. SCULLY. Correct me if I'm wrong. We have not reviewed a change in the set-up fee alone.

Dr. WELDON. So in front of this Committee, you are not saying it is inadequate or adequate?

Mr. SCULLY. I don't think we have come to that conclusion yet. I think, in looking at the other two components which are transportation, and the overall fee for doing the x-ray, where we have made—I don't think, the final rule should be out on November 1st, but the draft rule is pretty clear, that we have made some substantial increases in those areas. I think it was the biggest single increase in the physician fee schedule, but it probably isn't going to take care of all of their concerns.

Obviously, I am particularly concerned about making any additional changes up or down on the fee schedule that are really dramatic in the context of a negative 4.4 percent update. If we manage to fix that in the next 2 or 3 weeks, it will be a lot easier—I can tell you the anesthesiologists, the oncologists, many of the people think their practice expenses are off and they need higher payment. In the context, everybody is going down negative 4.4 percent, and everything is a zero sum game, it is difficult to make changes.

They are going to go up next year. It is not due to the set-up component. But the set-up component is $11, the transportation component varies, but it is about $100, and $30 is the x-ray. Roughly.

Mr. KAY. Roughly.

Mr. SCULLY. We will keep looking at the set-up component.

Dr. WELDON. Just so you understand. I am one of the people in this body who is trying to get you a better top line to deal with.

Mr. SCULLY. I would hope so.

Dr. WELDON. To help you in all of those areas. I do want to just cover the transportation issue. There is some regional issues associated with that. They vary by carrier. And I believe you delegate that issue to the carriers to make a decision; is that correct?

Mr. SCULLY. Yes.

Dr. WELDON. In the southeast, as I understand it, there is quite a bit of variability. And I have some serious concern the Florida carrier is under reimbursing this. And I would like you to look into this for me in the near future and get back to me about this. It is not unique, I believe, to Florida. There are some other States. It is one of the concerns I have. When you do delegate some of those reimbursement decisions to carriers, that sometimes they make good decisions and sometimes they make bad decisions.

So if you could please get back to me on that I would very much appreciate that.

Mr. SCULLY. I will tell you what I have done. I was traveling in Arkansas yesterday, but my crack staff, Dr. Trystla told me that you were concerned about Florida.

Dr. WELDON. How did he guess?

Mr. SCULLY. I think he heard from your staff. And, apparently one of the concerns—when this came up 2 years ago before I got to HCFA, now CMS, I believe that we actually discussed with the industry coming up with national rates for transportation. The ideas may vary among the industry, they decided that they didn't want to do that, they wanted to keep regional rates, which are set by the carriers.

I heard from Tim yesterday, that our carrier, which is First Coast in Florida, had not been, for whatever reason, particularly helpful in arranging a meeting with the portable x-ray suppliers. I called the CEO of First Coast last night. He didn't know anything about this. And I asked him to specifically meet with him and have his staff meet with them, and tell me what—they would decide what the appropriate rate is with First Coast, which is the Florida carrier.

But I will get back to him, and as soon as he meets with them and the industry will—it is for the industry to go in and make the argument about having a higher rate.

Dr. WELDON. Great. Mr. Chairman, I want to thank you so much for giving me the opportunity to be here. And I want to thank all of the witnesses, including, the impromptu witnesses for the input that they have helped us with.

I just want to, before I yield back, I would be very happy to linger. I just want to underscore, that I think this is a valuable service for seniors. I am determined to do everything I can to make sure that it remains a viable service for senior citizens.

Chairman MANZULLO. Thank you. The problem is that as what happened in Rockford, Illinois, the carriers went out of business. And it is costing the taxpayers a tremendous amount of money to do the same service that the portable x-ray people did, that—the portable x-ray people charge a fraction, by the time you figure when Ma had to go to the hospital, and one of those Caravans picked her up, it wasn't an ambulance, a special vehicle, and she was gone 4 hours. And that—that was the guy's only run. She was the only one in the van. She sat in the emergency room. I mean, the cost to the taxpayers is horrendous. And it continues. And my question, and Mr. Halsey, I am sorry to really put you on the spot. Forgive me for putting you at the table.

Mrs. Taylor, I don't apologize for that, you raised your hand, you came up here on your own. We run this Committee a little bit differently than some committees, but the purpose is to resolve issues. And that is why we are here.

Is there anything that we can do between now and January to prevent the further closing of these extremely important home x-ray businesses? I mean, is there—my understanding of the statute, Mr. Scully, is that you can have an interim payment system, that would at least keep these home x-ray providers alive, fulfilling that purpose, because they can get the finest ruling in January, but if they are all out of business, it wouldn't do much good at that point.

Mr. SCULLY. Well, Mr. Chairman, the suggestion——

Chairman MANZULLO. I am sorry. Interim rate adjustment.

Mr. SCULLY. Tim and Terry can jump in. The biggest variable, which is carrier priced, and varies by region, as you mentioned, is transportation. What we are planning to do is send out, I think it is just about to go out, a memorandum to all of the carriers, asking them to review this.

I think the message they will get from that is not to review it down.

Chairman MANZULLO. If they are like Wisconsin's Physician Service they * * *

Mr. SCULLY. Well, not all of them are like that. We have been—I have been trying, as you know, and I hope again in the next couple of weeks that we will. And there is bipartisan and bicameral support for carrier and contractor reform. We are trying to come up with the 20 best contractors.

Chairman MANZULLO. So are you going to ask them——

Mr. SCULLY. To go back in and review the transportation payment.

Chairman MANZULLO. Are you going to ask them to mark it up higher?

Mr. SCULLY. Well, we ask them to go back and review its appropriateness. That is probably 75 percent of the actual fee is the transportation cost. So if we send out a program memorandum saying we think there is a problem here, please go back and review it, cull this criteria, tell us why you set it at the rates you did, review that rate, get back to us, the general—they generally follow our guidance and go back and look at it.

Chairman MANZULLO. Mr. Halsey, would that satisfy your inquiry?

Mr. HALSEY. Mr. Chairman, I want to applaud the effort and point out that the program memorandum that is being discussed came about through these organizations working with CMS. I know we all bash an agency such as CMS with vigor and frequency.

We applaud that. That will, over a period of time, impact individual providers that are dealing with individual carriers. And we think that is outstanding. But we still would love to see the—when we talk about the highest rate, which this is statistically true of the overall update, we are talking pennies for patient. We might be talking 7 or 12 cents per patient. While that is appreciated, it isn't going to make any difference. These companies are going out of business. Our one request statutorily, and this is in response to the questions that the Committee put before Mr. Scully——

Mr. SCULLY. If we can get into the weeds a little bit on this. There are three—I am rounding off. Three basic components. The $11 set-up fee, which is a practice expense and has to go through a formal—there is a Federal rate for that. That has to go through a formal panel, which varies the rates relatively to other practice expenses and other doctors.

There is a $30 x-ray fee, which is the update, again a relatively small piece we are talking about. Then there is the roughly $100 transportation fee.

There is only one set locally, the transportation fee. It is by far the biggest component. If the carriers change that that will have—the other two pieces which are smaller are a part of a much more structured developmental national rates.

Chairman MANZULLO. Would you agree with that?

Ms. HALSEY. I am still stuck with the fact, and it was answered formally to Dr. Weldon's question. The statute clearly states that these are to be reviewed every 5 years. The answer is it has not. We are asking for an interim adjustment in recognition of the fact that this $11 rate was set 10 to 12 years ago.

I think it is reasonable to say.

Chairman MANZULLO. Which figure are you looking for?

Mr. HALSEY. The data we provided to the Agency places it between normal hours and after hours in the high twenties to low $30 rates, and that is in cost. And I understand it is not strictly cost-based now and that is appropriate. But certainly if we—what we are looking at is something over 100 percent increase is appropriate on the only data that exists, and that is the date that was compiled by our industry.

So what we are saying is in the absence of the legally mandated 5-year review and any data that has been put forward by CMS, it doesn't seem reasonable to set an interim adjustment until—and if in January they can get this going and everything else—let us be clear; in January it doesn't mean it is over, but an interim adjustment which is legally possible from the Secretary's office would give these small businesses the hope to say—because that is what we are talking about. They need a sign from this Agency that says I need to stay around.

Chairman MANZULLO. Did you want to respond to that, Mr. Kay or Mr. Scully?

Mr. SCULLY. I guess the way I have looked at it, as he said, the only evidence out there so far is industry data. And it is a rel-

atively small amount of money, in all candor. But on the other hand, it comes from a $66 billion pot of money that every time one goes up, others come down. In the context of making adjustments in that budget-neutral pot the physicians are very angry about right now, I have been hesitant to make any radical changes, even though this is a small amount of money.

The much bigger variable is transportation and it doesn't really count against that pot. So if a local carrier decided to go out and say we were going to pay $120 for transportation instead of $100, they just do that and it doesn't come out of the rest of the pot. So it looked to me as a more workable solution. We are happy to keep looking at the $11 but we have to come up with independent data other than what the industry gave us.

Chairman MANZULLO. The only reason, going to Dr. Weldon, that I would suggest that you increase it is the fact that it is obvious by any test whatsoever that you would be saving millions of dollars instantly by not sending these seniors in these caravans, tying up drivers for 4 hours. This is so simple; that if they get a modest adjustment on the cost of the x-ray, you won't—you will save immediately millions of dollars.

I use my mother as an example, because that is exactly what happened there. I would suggest—I mean, I can't force you. It does two things. We need to save this profession so they are around here in January; otherwise they are going to be gone. And the second thing it does is it automatically saves money.

Mr. SCULLY. We will aggressively keep looking at it. I think we have made a lot of changes in the policy. I think there is a strong likelihood the biggest component will go up. And to be honest with you, Mr. Chairman, there are very few things out of that $265 billion pot that I wouldn't structure differently if I could. There are a lot of crazy things in the budget.

Mr. WELDON. Mr. Chairman, I would ask you to yield to me for a minute. Are you saying, Mr. Scully, for you to provide an interim rate adjustment upward now for the setup fee for the portable x-ray providers, that you have to adjust somebody else down to find the revenue for that?

Mr. SCULLY. It depends. My belief is that that is correct because basically within the physician payment pot for anything we set rates for, which includes the general physician payments and the national—anything on the RBRVS scale—the physician gets 36 bucks for an office visit. If we decide to raise anesthesiologists' practice expenses or raise oncology payments, it comes out of the pot someplace else. And that is what this $11 setup fee is in the $66 billion pot that is in the national rate schedule.

On the other hand, when you leave something to carrier discretion and they make the changes during the course of the year, they can raise the rates temporarily it doesn't have an impact on anybody else. So the transportation fee can be raised locally without any impact on any rates; is that correct?

Mr. WELDON. Just so I understand, you know the reason I am bringing up this setup fee is it has been frozen at a 1992 level. And, you know, we have had some inflation since then. And are there other fees in that same pot that have been frozen at the same level for the last 10 years?

Mr. KAY. There are some that have actually gone down in the last 10 years. I was going to say basically this service—because you know, to date anyway, we haven't had data that sort of met the criteria that we use to establish these rates. Essentially the payment rate is—carried over from the previous charge based system. It used to be the reasonable charge system. And the new fee schedule was implemented in 1992, so we sort of used the average rate that was being paid at that time. And since then we have applied the updates over the years. So the various adjustments that have been made to the fee schedule have been applied to that rate.

Mr. SCULLY. So it has gone up a little bit but not that much.

Mr. WELDON. Before yielding back, I just want to say I am very concerned about the fact that the input I am getting from industry is the setup fee on this, the cost to the carriers, and I understand they can make it up on transportation perhaps, but I think there should be a basis in fact and a basis in logic and a basis in reality for the reimbursement schedule. And if the setup costs associated with these small businesses are 100 or 200 percent higher than the current Medicare reimbursement schedule, then I think it is very, very timely that we review this. And if at all possible, I would like you to provide an interim update for this service in the weeks and months ahead, and I would highly encourage you to do that.

I am happy to yield back.

Chairman MANZULLO. Mr. Kay, are you saying there is something flawed with the data that has been given to you by the industry?

Mr. SCULLY. I have gone through this now with the $17 billion outpatient rule which has moved payments for drugs in the country up and down. As a matter of course, we generally try to come up with independent third-party independent data.

Chairman MANZULLO. You don't have any other data; is that correct?

Mr. KAY. Right.

Chairman MANZULLO. So I mean, there has been no review in 5 years. You have no independent data on your own, and you could take the data of using my mother as an example. I mean, this is so simple. I mean, this is so simple. We are going into the flu season. And if my mother were still alive, I think I would lock that door there and post a guard and instruct you, Mr. Scully, to increase that schedule right away so she doesn't—so she wouldn't have to get into one of those ambulances, go out where it is cold, and sit in a waiting room with a bunch of sick people at a hospital. I mean, you could prevent that. It is so simple.

And these people are knocking on your doors. You have physicians all over the place saying, this is not an issue of money, this is an issue of safety and health of these patients. And people in nursing homes have no business being carted to a hospital and set in a waiting room with all types of germs and things when the reason they are there is perhaps probably because their doctor thinks they have pneumonia in the first place. I mean, we really need an answer on this thing.

I mean, can't you just—what does it take? I mean, you could make it an administrative rule, Mr. Scully, to say that at least until January, which is only, you know, 2½ months from now, 2¾

months from now, we are going to increase that x-ray component just so these guys can stay alive. I would implore you to do that.

Mr. SCULLY. Mr. Chairman, I think this thing has gotten a lot of attention in the Agency. I think there is a high likelihood that certainly with some carriers and some regions, the payment is set by region, which is the biggest piece. My biggest concern, to be honest with you, and a lot of physicians don't put two and two together, that if you ask Congressman Weldon, Dr. Weldon—I think he is an internist—can we increase any other fee in the pot? And by the way, we are going to cut your office visit for your next doctor's office visit by 50 cents—.

Chairman MANZULLO. So you would have to cut another? So the result of this hearing today is you are going to encourage the State providers to up the transportation fee to help these guys out in the interim.

Mr. SCULLY. We are going to tell them to do the right thing, but hopefully they will understand that they are supposed to review this thoroughly and, like I did with the CEO of the Florida health plan, when we find problems where we are not getting any satisfactory communication with our carriers from the industry, we will call them up and make sure they get a thorough hearing.

Chairman MANZULLO. Anybody else have anything they want to add?

Ms. TAYLOR. We are just very anxious for this program memorandum to get out. So hopefully it will get out very soon.

Chairman MANZULLO. Is there anything they can do?

Mr. SCULLY. I think the program memorandum is just about out the door. And if it isn't, it will be after this hearing.

Chairman MANZULLO. We are 3 for 3 today. Thank you so much, Mr. Scully. This is the sixth hearing we have had on CMS.

Mr. SCULLY. First on CMS.

Chairman MANZULLO. First one on CMS. But I don't think—let me put it this way. To the physicians out there and the providers, I can't tell you how much they appreciate your sitting down at a table like this with the people that make the decisions and the policy people. The dermatologists were actually shocked that they sat at the table with the person that said, come, be a part of this group.

I am shocked, pleasantly, pleasantly surprised, amazed it could be—I don't want to say this easy—but this is a process that we use to try to resolve things. You know one of our goals on the Small Business Committee is to bring down the cost of health care insurance and one of the ways we do that is to try to help you make CMS more efficient.

Mr. SCULLY. I will tell you, because I share your goal. As I told you before, we created 11 open-door policy groups with the same intent. I think we have had over 3,000 people on these calls. And once a month with every one of these groups—the hospitals, rural hospitals, nursing homes, home health agencies—last week I had one with pharmacists, last week I had one with three health providers, and we had about 40 people in Washington and something like 1,200 on the phone, and we go through all these issues and people bring up gripes and complaints and we try to fix them.

So maybe we should invite you to come co-chair one with me at some point.

Chairman MANZULLO. I would look forward to that after the election. Thank you again so much and this meeting is adjourned.

[Whereupon, at 4:25 p.m., the Committee was adjourned.]

Congress of the United States

House of Representatives

107th Congress

Committee on Small Business

2301 Rayburn House Office Building

Washington, DC 20515-0315

Statement of Donald A. Manzullo
Chairman
Committee on Small Business
United States House of Representatives
Washington, DC

October 3, 2002

On April 10, 2002, Mary Harroun, a small business owner, came to Washington, DC to testify about the regulatory treatment that her company, the Merry Walker Corporation, was receiving from CMS. She had expected Mr. Scully to hear her testimony concerning the benefits that her device, the Merry Walker®, would give to residents of skilled nursing facilities that are currently confined to wheelchairs.

This hearing is not just about one small business and her travails with CMS. Rather, it is about the rigidity of a statutory and regulatory regime that may impose substantial penalties on skilled nursing facilities, many of which are small businesses, in an effort to improve the quality of life for residents. The regulatory regime forces skilled nursing facilities to classify certain devices as restraints with the additional requirement of obtaining a physician's order and demonstration that the device is being used to treat a medical condition. Ambulation assistance devices, including the Merry Walker®, simply do not fall within that simple categorization. The Merry Walker® treats old age and the

infirmity that comes with it – not any specific medical condition. Nor is the Merry Walker® a device that will be used for a defined period of time. The resident may require the use of a Merry Walker® for the rest of their lives. Yet, skilled nursing facilities, and who can blame them, are not willing to take the regulatory risk and additional cost associated with using a "restraint." Would it not be better for residents in skilled nursing facilities to be ambulatory thereby reducing the incidence of muscular atrophy rather than being placed in a wheelchair out of regulatory fear?

Today's hearing will explore this issue, the statutory and regulatory framework that forces the skilled nursing facilities from purchasing the Merry Walker®, and potential solutions to the improper classification of devices designed for mobility assistance as restraints.

I will now recognize the gentlelady from New York, Ms. Velázquez, for her opening remarks and then will go to the Chairman of the Subcommittee on Regulatory Reform and Oversight, the gentleman from Indiana, Mr. Pence for his opening statement.

TESTIMONY OF
THOMAS A. SCULLY
ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
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AMBULATORY ASSISTANCE DEVICES
AS WELL AS
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BEFORE THE
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Chairman Manzullo, Congresswoman Velázquez, Chairman Pence, Congressman Brady, distinguished Committee members, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services' (CMS) evaluation of ambulatory assistance devices as well as clinical laboratories. As you know from my previous testimonies before this committee, President Bush, Secretary Thompson, and I are strongly committed to protecting the health and safety of this nation's most vulnerable citizens – the sick, the poor, the elderly, and the disabled. We also are dedicated to safeguarding the taxpayers' money in the Medicare trust funds, and to tearing down regulatory burdens for small businesses. We believe small businesses are critical to the future of our country, and I want to continue working with you to meet their needs so that they can continue to provide high quality care for Medicare beneficiaries.

Small businesses provide a variety of health care services. They include individual physicians, small group practices, and providers of durable medical equipment, orthotics, and other supplies and services. They help to ensure that Medicare beneficiaries receive the care they need and play a vital role in the Medicare program. I recognize the importance of helping small businesses continue to fill this need. Since I took over as CMS Administrator, my number one priority has been to improve the Agency's responsiveness and make it a better business partner. At CMS, we are committed to simplifying our rules, making them easier to understand and less burdensome. We also are committed to opening up CMS and creating more ways for the entities we regulate – including small business – to interact with us. This helps all sectors of the health care industry, of course, but we are paying particular attention to small business providers.

For example, one way we are making the Department, and CMS in particular, more open and accessible is through the Secretary's Advisory Committee on Regulatory Reform, which we created last summer and includes patient advocates, providers, and other health care professionals from across the nation. This Advisory Committee helps to guide the Secretary's efforts to streamline unnecessarily burdensome regulations and to eliminate inefficient regulations that interfere with the quality of health care for Americans. I know that you, Mr. Pence, and your Subcommittee have a particular interest in the Advisory Committee's suggestions on clinical laboratories, and I will discuss those in more detail in a few moments.

We also have created 11 "Open Door Policy Forums" to interact directly with beneficiary groups, providers, suppliers, physicians, and health plans to strengthen communication and information sharing between stakeholders and the Agency. These regular forums are open to all providers – rural, urban, small, large, for-profit, and nonprofit – and to the public. Many of these groups include small business providers. Outside groups meet with senior CMS staff on a regular basis, most of them monthly, to bring to our attention those nagging little problems that they encounter when dealing with the Medicare and Medicaid programs.

We also are working directly with physicians and other health care providers to improve our communications with them and ensure that CMS is responsive to their needs. We are providing free information, educational courses, and other services through a variety of advanced technologies. In particular, we have a broad selection of training materials available on our Medicare provider education website, www.cms.gov/medlearn. This site provides timely, accurate, and relevant information about Medicare coverage and payment policies, and serves as an efficient, convenient education tool for all providers, including small businesses.

As someone who has worked on health care issues in both Bush Administrations, as well as in the private sector, I know how frustrating Medicare's complex regulations can be. Simplifying the requirements and generally making Medicare a better business partner has been a top priority of mine for years. This Administration takes very seriously the importance of assessing the

impact of its decisions on all Americans, including small business owners, and I look forward to continuing to work with you to further improve the system.

CODING AMBULATION DEVICES ON THE MINIMUM DATA SET

Quality of Care

Over the last few years, at CMS we have focused intently on improving the quality of care for Medicare beneficiaries across the health care industry, including the nursing homes where nearly 3 million Americans receive care. Most recently, we began publishing quality data on individual nursing homes in six pilot States, and we plan to expand this project nationwide. Our goal is to educate beneficiaries and their families so that they can better compare their options and make the best choice for their own or their loved ones' care. To this end, we are publishing information about how individual nursing homes perform in nine measures of quality that were recommended by a broad-based committee of the National Quality Forum, an independent standard-setting organization representing public and private purchasers, consumers, providers and researchers. The nine measures are designed to help consumers make and "apples-to-apples" comparison of nursing homes. We are strongly committed to ensuring these Americans receive the excellent care they deserve and enjoy a high quality of life.

I recognize that ambulation assistance devices like the Merry Walker ® Ambulation Device are intended to help improve the quality of life for nursing home residents and others who face reduced personal mobility. This is a noble effort and I appreciate the people, including my fellow witness, who are working hard to create new and improved ways of enhancing mobility for these residents. I believe that there are numerous instances where these ambulation devices are used appropriately every day. However, I also am aware that there are some instances where devices like the Merry Walker® Ambulation Device are used in ways other than those intended by their manufacturer. While these devices are meant to help people become more independent, sometimes nursing homes uses them in ways that restrict the resident's freedom of movement and, in fact, can pose a serious and dangerous threat to the health and safety of some Medicare and Medicaid beneficiaries.

Results of Working Together

I have directed my staff to work closely with you to examine the way that ambulatory assistance devices like the Merry Walker® Ambulation Device are coded on the Minimum Data Set (MDS). We have met with Chairman Manzullo and communicated often and in detail about this issue. In fact, since in mid-June, when my staff met with Chairman Manzullo and Ms. Mary Harroun, whose company manufactures the Merry Walker®, over 40 e-mails and tens of hours of phone calls between our staffs have occurred, with the ultimate goal of streamlining our guidelines while ensuring compliance with the statutory requirements and resident safety.

As a result of these interactions, CMS has proposed changes to our Guidance to State Surveyors, and our Resident Assessment Instrument (RAI) Manual. The Committee's Regulatory Counsel approved these changes in July, and CMS sent proposed RAI changes for review by industry to ensure that the changes are understandable. These changes focused on the requirement that nursing homes assess whether a device, such as the Merry Walker® Ambulation Device, have the effect of restraining an individual. This change would alleviate the concern that facilities improperly code the Merry Walker® as a restraint in every instance, without doing an individual assessment. I am pleased with the level of cooperation we have achieved to ensure that devices are coded correctly on the MDS assessment tool and that nursing home residents are properly assessed and cared for without being put at risk. Although I understand Chairman Manzullo still has concerns that these changes do not go far enough, it is only when we work together in this fashion can we have the most appropriate impact and create the greatest good. I look forward to continuing to work with you in this manner.

Legal Requirements

The Nursing Home Reform Act of 1987 state that the resident has "the right to be free from ... any physical or chemical restraint imposed for purpose of discipline or convenience and not required to treat the resident's medial symptoms. Restraints may only be imposed (I) to ensure the physical safety of the resident or other residents and (II) only upon the written order of a physician that specifies the duration and circumstances under which the restraints are to be used." CMS defines a physical restraint in a nursing facility as "any manual method or physical or

mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily that restricts freedom of movement or normal access to one's body." As described below, in one section of the MDS nursing homes are required to answer whether the facility uses a restraint on a particular resident.

The Minimum Data Set

The MDS is part of our Resident Assessment Instrument, which is used to develop a comprehensive assessment for all residents in a long term care facility certified to participate in Medicare and Medicaid. Specifically, the MDS is a set of screening, clinical, and functional elements that helps to give staff a better understanding of the health status of each resident. As a screening tool, the MDS helps nursing home staff to identify possible problems that need to be addressed in a resident's individual care plan. As part of this assessment, we capture information on any device that meets the definition of restraint. That includes recognizing any time a device like the Merry Walker® Ambulation Device meets the definition of restraint for an individual resident.

We have focused on improving how facility providers code information on our MDS form. Providers use the data from the MDS as a part of the assessment and care planning process required by law for residents in nursing homes certified for Medicare and/or Medicaid . The current version of the MDS was developed in 1995 with considerable input from countless individuals representing associations, beneficiary groups, and State governments with which we have worked in partnership in implementing the MDS nationally. We recognize the value of including different perspectives and areas of expertise in establishing clinical guidelines and plan to continue this open and inclusive approach with refinements to the MDS to streamline it and get nursing staff back to the bedside and caring for residents, not filling out paperwork.

I understand this Committee is concerned about how ambulation devices like the Merry Walker® Ambulation Device are coded on the MDS. Evaluators code ambulation devices as a mode of locomotion and/or a physical restraint, depending on how the device impacts the individual resident. As noted above, the Nursing Home Reform Act guarantees nursing home residents

freedom from restraints being used for the convenience of staff. Our State Operations Manual, which guides state surveyors, defines a physical restraint as any "device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily that restricts freedom of movement ...." If a nursing home resident cannot open the front gate on an ambulation device due to physical or cognitive limitations, and so cannot exit the device, the device restricts the resident's freedom of movement, and must be coded on the MDS as a restraint. Conversely, if an ambulation device were not restrictive for a resident, it would not need to be considered a restraint.

The Merry Walker® assessment sheet itself recognizes the distinction between when the device is a restraint and when it is not. The written materials accompanying the Merry Walker® state: "If a resident can remove himself/herself from the Merry Walker then it is not a restraint." We agree and have instructed nursing home providers to code this device as a restraint only in those instances where the resident cannot remove himself from the device.

Statutory Requirements for Using a Restraint

Even if the device meets the definition of a restraint for an individual resident, that would not necessarily prohibit the device's use. If there is a medical symptom that warrants the use of the restraining device, the resident could still use it, provided that a physician prescribes its use. The law prohibits the improper use of restraints in order to ensure that nursing home residents retain their right to be free of restraints for discipline or convenience of the nursing home's staff. It is permissible and appropriate, however, to use restraints when treating a medical condition or to ensure the safety of the resident. The nursing home, in conjunction with a physician, must perform an assessment to identify the medical symptoms the restraint would be employed to address. The assessment should take into consideration the professionally and medically recognized risks of using the device versus the potential risks of not using the device for that particular resident.

State Surveyors Citations Involving the Merry Walker®

Recently we reviewed state surveyors' citations delineating the inappropriate use of restraints over this past year. Of the 6,103 citations written by surveyors for inappropriate physical restraint use, approximately 30 involved the use of the Merry Walker® Ambulation Device or similar device, or less than one half of one percent. These numbers suggest that state surveyors understand the regulations involving physical restraints and generally have correctly cited facilities for improper use of the Merry Walker® Ambulation Device. More importantly, our review of the citations indicates that for the vast majority of the time the Merry Walker ® Ambulation Device does not meet the definition of a restraint. If the device should be considered a restraint for a particular resident, facilities are properly assessing the device, monitoring its use, and following the rules set out in law involving when a physical restraint can be used.

It is incumbent upon facilities to properly assess whether this device meets the definition of a restraint for a particular individual, and this assessment must be ongoing. When a resident cannot exit the device on his own accord, additional oversight of the resident is required. Some of the deficiencies found by state surveyors involve the Merry Walker® Ambulation Device as a restraint. In some cases the device caused actual harm to the resident. These cases highlight the need for CMS to be vigilant in protecting nursing home residents from the inappropriate use of restraints.

Injury Sustained While in the Merry Walker® Because of Inappropriate Use or Inadequate Supervision

Some surveyors found cases of residents who could not open the gate on the Merry Walker® being injured as they attempted to get out of the Merry Walker® Ambulation Device by crawling out from under the gate or trying to climb out over the top of the gate. In other cases, the residents were injured while using the Merry Walker® Ambulation Device. When properly used, the device prevents falls (as the manufacturer intended). However, without appropriate supervision, particularly when the device limits the resident's freedom of movement, significant harm may occur.

- One state surveyor uncovered an instance in which a resident had fallen on six separate occasions while using the Merry Walker®. The resident attempted to get out of the device by sliding out from under the gate, since she had such difficulty opening the gate and exiting the device. In the same facility, a resident fractured her arm when she tried to climb out of the Merry Walker® Ambulation Device, and another a resident fractured his hip while trying to climb out of the device.
- Another example of actual harm involving the Merry Walker® Ambulation Device included a case in which the survey team heard the resident yelling for help. The surveyors found the resident lying partially across the bed. The resident's foot and leg were caught in the seat strap of the Merry Walker®. While his foot remained trapped in the device, the Merry Walker® began rolling away from the resident, putting him at risk of being pulled to the floor by the ambulation device. Interviews with staff confirmed the resident had tried to get out of the Merry Walker® on other occasions and had sustained falls while in the Merry Walker®.
- One resident overturned the device and was found on the floor with the device on top of him. The resident was injured by the fall. Despite his repeated falls while in the device, staff continued to state the device was used to prevent falls and failed to reassess the resident's needs. In this case, a staff member admitted that the use of the restraint without assessment could pose the risk of death or serious physical harm, and concluded that facility should have assessed the resident's use of the Merry Walker®. The staff member noted that the use of the restraint without assessment could lead to functional decline (such as incontinence) for a resident. Review of the record revealed that by the time the facility assessed the resident occurred, the resident had sustained multiple falls, needed greater assistance in locomotion, and had become incontinent of bowel and bladder.

Improper Use of the Merry Walker® for Staff Convenience

The Nursing Home Reform Act prohibits the use of a restraint for staff convenience. State surveyors uncovered instances of where nursing home staff used the Merry Walker® to keep residents from wandering. When a resident is unable to open the gate on the Merry Walker®

Ambulation Device without assistance or does not understand the instructions given by the staff on how to open the gate on the Merry Walker®, staff may not place the resident in the Merry Walker® for convenience.

- State surveyors cited one facility for restraining a resident in a Merry Walker® Ambulation Device for staff convenience. The Merry Walker® kept the resident from leaving the building. Surveyors found that staff would leave the resident in the Merry Walker® when they could not supervise her, even though the staff had not assessed the appropriateness of the resident's use of the Merry Walker® and staff had not identified the use of the restraint on the resident's care plan. A certified restorative aide and charge nurse revealed that the resident did not need restorative services because the resident was able to walk without the use of the ambulation device. However, staff noted that the resident could not exit the device on her own, but she would attempt to get out of the Merry Walker®, because the Merry Walker® agitated the resident.
- State surveyors cited a facility for placing a resident in the Merry Walker® all day, including leaving the resident in the device for meals. The staff would place the resident's meal tray on the Merry Walker®. The staff admitted they did to restrain the resident, who could not exit the device without assistance. When not in the Merry Walker®, the resident would attempt to get up leave the table and walk around.

CMS does not prohibit the use of restraints, but rather establishes procedural safeguards to protect residents from their overuse. We acknowledge that there are situations where restraint use is both appropriate and necessary. When the Merry Walker® is considered a restraint in a particular instance, it may be properly used with a plan of care. However, as the above examples make clear, the protections required are appropriate for those instances in which the Merry Walker® meets the definition of a restraint. The examples of the device's inappropriate use and/or inadequate supervision caused injury to the resident emphasize why we focus on the effect the device has on the resident and not merely the manufacturer's intent on making the device. While we are strongly committed to our efforts to support small businesses, we have an obligation to uphold the statutory right of a resident to be free from a restraint that is used for

staff convenience or where the medical symptoms do not warrant.

While I have cited a number of instances where these ambulation devices have endangered nursing home residents, I am certain there are numerous instances where the devices have had very positive impacts on the lives of residents. We want to increase the number of positive stories and decrease the instances of risk to nursing home residents. One way we can do this is to ensure nursing homes follow the statutory mandate that they complete comprehensive assessments and provide individualized plans of care for each resident. In this way, we can help facilities understand what constitutes a restraint and understand when restraint use is appropriate and inappropriate. We have been working hard to simplify our procedures and make Medicare a better business partner for health care providers so they can better understand their responsibilities and have more time to care for our beneficiaries.

We require nursing home evaluators to determine whether devices like the Merry Walker® Ambulation Device should be coded as a restraint based on its effect on each individual resident. This enables us to better ensure that we are protecting the resident's right to be free from the inappropriate use of restraints as mandated by the law. We are doing everything we can to make it easier for health care professionals in nursing homes to provide appropriate care for their residents -- including improving our working relationships with small businesses while maintaining regulations that are in the best interest of nursing home residents and the taxpayers. As I said earlier, I appreciate this Committee's dedication to that end, and I look forward to continuing to work with you in this effort.

CLINICAL LABORATORY REGULATION

In addition to ambulation assistance devices, at CMS we also regulate clinical laboratories under the Clinical Laboratory Improvement Amendments (CLIA). A precursor to CLIA was passed in 1967 with CMS's regulatory responsibility limited to those laboratories that participated in the Medicare and Medicaid programs, and laboratories that tested specimens in interstate commerce. Congressional hearings over the concerns about deaths of women from erroneously read Pap

smears and the proliferation of bench top laboratory technology into non-traditional testing sites led Congress to amend the original CLIA law.

In 1988, Congress passed CLIA, expanding CMS's responsibility to include all laboratories that test human specimens "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." We implemented those changes in 1992 with the publication of a final rule with comment period. The law sets minimum uniform quality standards for all clinical labs and was passed with broad bipartisan support. It is an important program that helps to protect all patients, including Medicare beneficiaries, by encouraging accurate, reliable lab test results and timely reporting of those results.

We know one way to make a program like CLIA even more effective is to make it more user-friendly for providers. That is why we have worked hard to streamline procedures, improve flexibility, and reduce burdens on labs. We also are working to take into consideration the tremendous amounts of feedback we have received on the 1992 rule so that we can publish a streamlined final rule in the near future. We think this will be especially helpful for the small business labs that many Medicare beneficiaries and others rely on for their health care needs.

CLIA regulations are based on the complexity of tests, not the type of lab or where the testing occurs. Labs performing similar tests must meet similar standards, whether located in a hospital, doctor's office, or other site. Under CLIA, there are three categories of tests: waived tests, moderate complexity tests, and high complexity tests. The most frequently performed tests in physicians' office laboratories are waived tests -- simple tests with small chance of error or risk – which are exempt from routine surveys and virtually all CLIA rules. Labs performing only these tests are referred to as Certificate of Waiver (COW) labs. Although exempt from many rules, they must enroll in CLIA, pay a certification fee, and follow the test manufacturer's instructions.

Moderate and high complexity tests are subject to a number of CLIA requirements, including:

- Personnel: CLIA sets minimum qualifications for all persons performing or supervising moderate or high complexity lab tests.
- Proficiency testing: Labs must also participate in an approved proficiency testing program, which provides an external evaluation of the accuracy of the lab's test results.
- Quality control: Labs must have a process for monitoring personnel, testing equipment, and the testing environment to ensure proper operation and accurate results.
- Quality assurance: Labs must have and follow a plan to monitor, on an ongoing basis, the overall operation of the laboratory, provide communications and resolve problems that affect the quality of their testing.
- Cytology testing: CLIA sets special rules for cytology testing including workload limits, individualized proficiency testing and personnel standards, and quality control procedures.

Data show that these regulations are helping. Since CLIA was implemented in 1992, quality deficiencies on clinical labs overall have decreased significantly. The first onsite surveys of labs revealed that up to 35 percent of labs had quality issues. At this time, less than 9 percent of labs have quality problems. We believe that our educational rather than punitive approach has facilitated improvement in lab quality. Data from our Survey Evaluation Form show that most laboratories respond very positively to the educational, information-sharing approach to oversight.

However, despite these improvements, the potential for safety-jeopardizing problems still exists, as shown in recent data on waived labs that are not routinely overseen. For example, under the CLIA program, we conducted an initial pilot study in the States of Colorado and Ohio, with on-site visits to a random sample of 200 labs that are exempt from many CLIA requirements. Significant quality and certification problems were identified in over 50 percent of these laboratories.

We expanded this pilot to include eight additional States to verify the scope and seriousness of Colorado's and Ohio's initial study findings. As a result of this expanded pilot, quality problems were identified that corroborated the initial study findings, which included:

- 32 percent failed to have current manufacturer's instructions for the tests they performed;
- 32 percent didn't perform quality control as required by the manufacturer; and
- 16 percent failed to follow current manufacturer's instructions.

Recent studies conducted by the CDC, HHS Office of Inspector General, and New York have produced similar findings.

Due to the significant increase in the number and types of tests waived, the rapidly expanding number of laboratories with no oversight, and the serious findings in COW laboratories, in April 2002 we notified State Medicaid Directors, organized medicine, professional organizations, and accrediting organizations that we would begin working with labs that are exempt from CLIA requirements to help ensure higher quality care. We are using an educational approach to help them enhance their basic lab practices and improve testing accuracy so they can better serve all Americans.

We started visiting 2 percent of the COW laboratories on April 15, 2002. The laboratories are notified in advance, first by letter and then by telephone, to confirm the on-site visit. The visits focus on the education of testing personnel to ensure quality testing. If quality problems are found, we provide assistance to the laboratories to help ensure they are able to achieve accurate and reliable results. There is no fee charged to the laboratories at this time for these visits, and we are pleased that our preliminary follow up data from our expanded pilot studies indicate this educational approach to be highly effective. Moreover, we are beginning to explore and develop other educational efforts for these laboratories to further help them improve the quality of services that they are providing to Medicare beneficiaries and others.

In addition to this educational approach, I want to mention a few of the other ways we have worked to reduce burden for providers, including many small business providers, that are subject to CLIA rules, as well as some ideas we have for future initiatives. Ninety-seven thousand, or 60

percent of all labs registered under CLIA, are small physician office labs (POLs). Although most of them face minimal regulation under CLIA, or have virtually all of their requirements waived, 22 percent of the POLs perform moderate or highly complex procedures that, if done incorrectly, could place patients at significant risk. So we have taken numerous steps over the years to help relieve burden for them. For example, in 1993, soon after CLIA was implemented, we defined a sub-category of moderate complexity tests, now called "provider-performed microscopy" (PPM), that are exempt from routine inspections under CLIA. In 1995, we expanded the PPM sub-category to many more labs by allowing dentists and mid-level practitioners to perform PPM tests, in addition to physicians. In fact, our data indicate that there are now more POLs enrolled in CLIA than there were at the outset. A 1997 OIG study about CLIA and access to laboratory testing likewise concluded that there had been no loss of access as a result of the CLIA regulations.

Of course, many labs that perform moderate or high complexity tests are not exempt from CLIA requirements, and for them CLIA is flexible in providing options for how quality standards may be met by allowing a number of options for private accreditation and State certification. Accrediting organizations currently approved by HHS for this purpose include COLA (formerly Commission on Office Laboratory Accreditation), the Joint Commission on Accreditation of Healthcare Organizations, and 4 others. Moreover, labs in States that approve or license labs under standards at least as stringent as CLIA are exempt from CLIA requirements.

To further help labs that are subject to CLIA inspection, we revised our survey procedures so that labs with excellent compliance records and proficiency testing scores will be inspected on-site less frequently. These labs may complete a self-assessment questionnaire in lieu of an on-site inspection in every other 2-year survey cycle, so they would be inspected on-site only every 4 years. Laboratories selected for this "honor" frequently comment how proud they are to receive this recognition. Furthermore, our surveys focus on lab practices directly related to the accuracy of test results or potential risk to patients, not impractical, burdensome requirements.

We also gradually phased in our personnel provisions to assure adequate time for lab staff to qualify. Most physicians already met all of the required qualifications. Moreover, regulations published in 1992 and 1995 allowed many lab employees who already were performing or supervising moderate or high complexity tests to continue to do so based on their training and experience.

Other important ways we have worked to reduce CLIA's burden on providers include:

- All routine inspections are scheduled ahead of time, rather than unannounced;
- Labs need not reapply for a new certificate for each 2-year survey cycle. They need only confirm their status and note any changes they have made;
- Implementation of quality control and proficiency testing requirements was phased in over time and technical assistance provided, if needed; and,
- Labs may use existing systems or processes to meet CLIA requirements, such as using the patient chart to record test orders and results, and manufacturer's instructions for a procedure manual.

FUTURE CLINICAL LABORATORY EFFORTS

Last summer Secretary Thompson created an Advisory Committee on Regulatory Reform, which includes patient advocates, providers, and other healthcare professionals from across the nation. This committee is helping to guide the Secretary's efforts to streamline unnecessarily burdensome regulations and to eliminate inefficient regulations that interfere with the quality of health care for Americans. We recognize that these requirements can have a disproportionate impact on small business providers who often do not have the resources that larger providers use to mitigate the effects of such burdens; and we believe that providers should focus on patients, not on paperwork. This Advisory Committee has developed a number of recommendations to help make CLIA more user-friendly for small businesses and all providers, including some we plan to work on in the near future:

1. ***Simplify and clarify the CLIA requirements using plain language when possible to assist laboratory and POL staff in understanding and complying with guidelines.*** We

plan to include clarified and streamlined language in the final CLIA regulations that we hope to publish later this year. Status: Workgroups to develop user-friendly guidelines for compliance are already convened. Input from POLs, professional and accreditation organizations, and experts will be solicited on these guidelines prior to publication.

2. ***Provide information to POLs about training opportunities by the State survey agencies and other accrediting bodies such as the College of American Pathologists and COLA to assist with interpretation and implementation of new CLIA requirements.*** Status: COLA already has several educational programs available for laboratories to meet all categories of CLIA requirements. We plan to work with all accrediting bodies to facilitate compliance following the publication of the final regulations.
3. ***Update the CLIA website, and develop a more user-friendly website with links to the Centers for Disease Control's National Laboratory Training Network (NLTN).*** Status: Discussions are underway with the NLTN, and our CLIA website, www.cms.gov/clia, is updated regularly with new policy and compliance information.
4. ***In the application package, include the CLIA requirements and a basic laboratory practices document in plain language tailored to the POLs test system menu for moderate complexity tests.*** Status: We are working with lab test manufacturers to develop a Basic Laboratory Practices document. One is already used as part of the COW survey project.
5. ***Help laboratories interpret the CLIA requirements.*** Status: Through our contract with the State Agencies, we are always available to provide technical assistance or resources for laboratories, and we are considering other ways that we can help provide guidance.
6. ***If compliance surveys are performed by CMS on waived laboratories, the evaluations should be according to CLIA guidelines and using criteria established in consultation with accrediting agencies and physician organizations.*** Status: We included feedback from many entities in the questionnaire for waived laboratory visits and we have just recently updated it again based on further comments, both internal and external.
7. ***Modify the Alternate Quality Assessment Survey (AQAS) self survey form, which includes questions about compliance with CLIA quality assurance requirements and is used to reward exceptionally good laboratories, as an educational tool to facilitate the survey and certification process.*** Status: Many individuals and organizations already

use this form for training and understanding Quality Assessment concepts. It is available on the CMS CLIA website at: www.cms.gov/clia. We will also consider new ways that we can improve this form.

8. ***Increase the number of POL representatives serving on the Clinical Laboratory Improvements Advisory Committee (CLIAC), to more accurately reflect the number of POLs being regulated.*** Status: Many of the members of the current CLIAC have owned or operated POLs, and we will continue to look at ways we can ensure POLs are accurately represented.

The Committee also had some longer-term recommendations, including:

1. ***Offer training and simplified guidelines to assist laboratories with new CLIA requirements at meetings of laboratory professionals, accreditation bodies, and medical organizations.*** Status: CMS and CDC representatives are always available to speak and teach at organized professional, State, and regional meetings and do so quite frequently. This is a valuable outreach tool that we will consider expanding.
2. ***Collaborate with the CDC on an educational brochure for POLs containing plain language interpretation of the regulatory requirements.*** Status: We have begun discussions with CDC.
3. ***Provide open forums with professional, medical, and accreditation laboratory organizations to solicit feedback on ways to improve outreach to POLs and to increase understanding of the CLIA program among physicians.*** Status: As mentioned, we always make CMS and CDC representatives available to attend various professional meetings, and we will consider expanding this outreach tool.
4. ***Solicit interest in developing an educational "Clearinghouse" on the CLIA website that includes a multimedia educational program package. Interested parties would include: CMS, other Federal agencies, professional, medical and laboratory accreditation organizations, and CLIAC. Methods for evaluation of the effectiveness of educational programs should be designed.*** Status: A Clearinghouse of educational programs for laboratories is being compiled and includes information received from States, professional, and accreditation organizations.

5. ***Collaborate with States and private laboratory organizations to develop and promote self-assessment tools for laboratories, as well as other types of educational programs. These should include an evaluation of effectiveness.*** Status: We plan to work with professional organizations to develop further self-assessment tools and we have already had one preliminary discussion. We intend to develop mechanisms to measure education effectiveness as part of the plan.

While we have worked hard to streamline and simplify the administrative requirements of CLIA so that we can better ensure high quality care for all Americans, we know that we have more to do. The Secretary's Regulatory Reform Advisory Committee suggestions offer us a roadmap for further improvement. We have a number of initiatives underway already, and have additional plans in development.

CONCLUSION

With both ambulation assistance devices and clinical labs, our priority is ensuring the health and safety of Medicare beneficiaries. We also are working hard to streamline our requirements and make Medicare a better business partner for all providers, including small businesses, because when these providers better understand and comply with Medicare regulations, they can spend more time caring for patients. I appreciate this Committee's continuing interest in the Medicare program, and I will continue to work with you as we improve further. Thank you for inviting me to discuss these issues with you today. I am happy to answer your questions.

House Committee on Small Business

"CMS Regulation of Healthcare Services"

Centers for Medicare and Medicaid Will Change Status of Merry Walker® Ambulation Device From Chair Prevents Rising to Adaptive Device /Restraint Alternative

October 3, 2002

Prepared Remarks of Mary M. Harroun, MS, LNHA

My name is Mary M. Harroun and I thank Chairman Manzullo and the House Small Business Committee for hearing my testimony today to resolve a seemingly small matter of wrongful classification by Centers for Medicare and Medicaid Services of a product known as the Merry Walker Ambulation Device which when scrutinized on a wider focus, has resulted in destructive medical consequences for all the 1.8 million residents of long term care facilities throughout of country today.

I come here today with thirty years of experience and expertise in knowing the importance of ambulating the long-term care field. I hold a master's degree in geriatric psychology and an Illinois nursing home administration license. Back in 1987 when the OBRA Regulations for Nursing Home Reform were passed by Congress, I became aware that the restraint issue had finally been addressed. Prior to the passage and enactment of the Regulations, most residents living in long term care had a very high potential of being placed in a wheelchair with a Posey vest that kept them tied to the wheelchair, thus being unable and soon, thereafter, incapable of walking. As the activity director of a long term care facility, I looked around the dining room one day and said to myself, all these people walked once, why are they not walking now? Upon reflecting on the idea that the residents before me that particular day were not walking, I started to design a product that would serve their needs by getting them up and walking once again and would allow them to walk restraint free. Since I am a mother of two children, and in particular reflected upon my son who really wanted to walk at birth, but was placed at a early age in a baby walker with a seat and wheels so that he could be mobile. I took that concept and after much designing, invented the product known today as the Merry Walker. One of the biggest problems I had in the development of the product was getting the residents in and out of the device safely. I lifted my son into and out of his walker, but I could not design a product that would require another person to lift the elderly person into a Merry Walker. This problem had to be solved. The front gate was designed to open like a fence gate out and away from the end user. The safety factors were foremost in my mind as I was designing a product that would allow very frail elderly to walk independently, but safely. Since the design of the product required that the Merry Walker enable them to walk safely, the elderly resident was required to hold onto the front gate in order to use the product, so the front gate had to be safely secured to the product, hence the reason for the swell latch. Merry Walker went through the normal steps of patent and trademark application and was placed on the market in the fall of 1990, to answer the OBRA Regulations and Guidelines of residents being free of physical restraints.

The marketplace accepted the product, but with any new idea on increasing quality of care for the residents of long term care, mindsets had to be changed from automatically placing a

resident in a wheelchair, should be resident be at risks for falls, instead of strengthening the resident by placing the resident in a Merry Walker. The product became so popular and such a demanded product, that at one time I counted eighteen copycats of my product, the Merry Walker, on the market.

At the Alzheimer's Disease Education Conference held in Chicago, July, 2001, I discovered that the Minimum Date Set had a User's Manual to instruct end users on how to use the Minimum Data Set for their residents. On page 3-158 under Devices and Restraints, it states under Intent: To record the frequency, over the last seven days, with which the resident was restrained by any of the devices listed below at any time during the day or night. Under definition: This category includes the use of any device (e.g. physical or mechanical device, material, or equipment attached or adjacent to the resident's body) that the resident cannot easily remove and that restricts freedom of movement or normal access to his or her body. Then it lists full bed rails, other types of bed rails used, trunk restraints, limb restraints and then chair prevents rising. Under this category lists any type of chair with locked lap board or chair that places residents in a recumbent position that restricts rising or a chair that is soft and low to the floor (e.g. bean bag chair). Includes "comfort cushions" (e.g. lap buddy), "merry walkers."

As you can see, Merry Walker is not a chair that prevents rising. Since CMS has no other categories to place the device in, even though Steve Pelovitz suggested in a letter written to me in March 2002 that of placing the Merry Walker under one the other restraint categories of full bed rail, trunk restraints, limb restraints, it still should not be considered a restraint because it does not describe the device. Due to this erroneous listing, all residents, about 65% of them have been wrongly placed in wheelchairs, and usually with chair alarms, therefore keeping the resident's total mobility restricted, which are the direct causes of CMS advocating poor quality of care for the 1.8 million residents in long-term care.

Due to the MDS and the impact of placing the Merry Walker under chair prevents rising, most of the copycats are no longer producing their version of the product, not because the product concept is not valued among CMS staff and nursing home professionals, but because of the listing as a chair that prevents rising under the MDS.

Walking, once it is learned as a baby, becomes an involuntary function for use during one's entire life, which is directed by the cerebellum, located in the lower back of the brain for safekeeping. Walking is not forgotten throughout the process of aging, unless the elderly are placed in wheelchairs and subsequently taught not to walk due to possible falls, placement in a wheelchair with a chair alarm and by disuse of muscles used for walking. Diseases and aging factors may slow down the process of walking, but the process of aging does not stop an elderly person from walking. Even Alzheimer's diagnosed elderly do not stop walking, in fact walking increases during the disease process, but they do exhibit gait and balance problems, often confused with walking problems, subsequently place those residents in wheelchairs with alarms so they never walk again. The nursing homes, but mainly the Centers for Medicare and Medicaid Services are directly responsible for causing the elderly not to walk by allowing the use of wheelchairs for up to 65% of nursing homes residents, not from disease or the normal aging process.

The costs of caring for a resident in a long term care facility who has become non-ambulatory is in the billions of dollars, due to increased falls and pressure ulcers when the simple solution was invented twelve years ago, but due to the fact that the Merry Walker has been considered a restraint, and involves long, long paper work for nursing home staff to complete, the Merry Walker has become very difficult, if not impossible for nursing homes to use this device for their residents to keep residents ambulatory. MDS is an assessment instrument to measure residents physical,

mental, and psychosocial status and nursing homes are required to fill out long involved assessments, presently covering about 400 items for each resident entering a Medicare/Medicaid facility in order for the facility to retain its Medicare/Medicaid certification and receive reimbursement from the government for the cost of care for their residents. The nursing home staff, from owners, directors, directors of nursing, and administration today live in fear of negative surveys and subsequent possible citations on deficiencies that might be found, that ultimately might threaten the financial existence of the facility. So when Merry Walker appeared in 1995 in the MDS under chair prevents rising, since the required paper work was so involved in getting a resident into a Merry Walker, the facilities, which saw, by then, the benefits of the device, could not use it for fear of deficiency citations.

In 1995, the Minimum Data Set appeared, to assess all residents in long-term care in order for the facilities to meet the standards of eligibility for Medicare payments. This assessment process involves problem identification and the care plan that evolves from this assessment process becomes each resident's unique path toward achieving or maintaining his or her highest practicable level of well-being for all nursing home residents throughout the country. It must be pointed out that the OBRA Guidelines are called the minimum standards for health care. All facilities must meet the minimum standards in order to quality as a Medicare certified facility.

We recently received thirty citations out of thirty-two citations cited by Leslie Norwalk in an email to Barry Pineles on August 1, 2002. The email states from Leslie,
" that I also wanted to give you some additional information regarding the number of times that the Merry Walker has been cited as a restraint. We reviewed all 57 physical restraints deficiencies that had the words "merry walker" in them. After a closer look only 32 deficiencies actually included the Merry Walker as the device used as a restraint. The other 25 cases had the words "merry walker" in the text of the deficiency but it might state something like "physical therapy recommended a merry walker be used by the resident..." In at least one case the surveyor questioned whether the facility had considered using a Merry Walker ® instead of a wheelchair. So on actuality, since 6/1/01 the Merry Walker was cited as an inappropriate restraint in only 32 of a possible 6103 physical restraint deficiencies or .05% of the time."

In reading through the deficiencies it became quite apparent that all the deficiencies cited were due to lack of paper or document compliance. The MDS requires documentation for all care given to a resident. In order for a resident to benefit from using the Merry Walker, I counted the possibility of the requirement of 32 documents in the residents medical care plan in order for one resident to use a Merry Walker. From the citations, I found the following deficiencies due to documentation error. It must be noted that I have not been trained in using the MDS, but these 32 documents were cited as not being part of the residents medical record or not complete therefore the facility received a deficiency on using the Merry Walker. They are the following:

1. **MDS standard assessment**
2. **Interdisciplinary care plan**
3. **Incident report on accident involving falls**
4. **Fall risk assessment**
5. **RAP sheet for restraints**
6. **Must indicate resident using chair prevents rising**
7. **Post fall investigation report**
8. **Significant change assessment**
9. **Systematic process for evaluation and care planning**
10. **Pre-restraining assessment**

11. Restraint assessment to see if resident can open the front gate on demand
12. Nursing assessment to see if resident is appropriate for Merry Walker
13. Interdisciplinary team restraint assessment
14. Physical therapy evaluation for ambulation potential
15. RAP sheet for behavior
16. Doctors orders listing specific medical symptoms for restraint
17. Doctors orders listing specific times Merry Walker is to be used by resident
18. Family and resident informed about the risks of using restraints
19. Family or resident consent form allowing the use of restraints and understanding the negative effects of restraint use
20. Explanation of functional declines that might occur with using restraints
21. Restorative care assessment
22. Assignment to restorative care schedule
23. RAI assessment
24. Updated care plan once Merry Walker is being used by resident
25. Restraint use form
26. Continual charting on resident evaluation of restraint use
27. Plan in medical chart for systematic reductions of restraints
28. Documentation that restraint was released every two hours
29. Comprehensive device assessment
30. assessment to determine that the least restrictive restraint is being used
31. MDS quarterly assessment
32. Continuation of updated doctor's orders for medical symptom

According the listing of the deficiency citations, all of these documents must be in place in order for a resident to use and benefit from the Merry Walker. If a facility had twenty-five Merry Walkers to assist 100 of their residents to walk, the facility would need 800 separate documents in place or risk receiving deficiencies for using a product that benefits their residents. Do we dare ask how much documentation is required to place a resident in a wheelchair? None!

What happens to an elderly person once they reach the nursing home level of care? Most residents are admitted from hospitals and they receive the care allowed under the Prospective Payment System, which allows $1500 for physical therapy and $1500 for occupational and speech therapy. Once that money runs out, about 20 days worth of intensive rehabilitation care, the resident is then removed from the Medicare bed and released to go home or placed in the long term care section of the facility. They will not receive physical, occupational or speech therapy once they reach the long term care section of the facility. So now the physical and mental deterioration problems start for this resident. If the resident is at risk for falls, they are immediately placed in a wheelchair. Under Regulation F279, the services that are to be furnished to attain or maintain the resident's highest practicable physical, mental and psychosocial well-being and required under paragraph 483.25, which reads a resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that diminution was avoidable. This includes the resident's ability to bathe, dress, and groom, transfer and ambulate. Under the Guidelines it states deterioration of a resident's physical or mental disability while receiving care to restore or maintain functional abilities. Under Procedures of 483.25, under Guidelines to surveyors, ambulation means how a resident moves between locations in his/her own room and adjacent corridor on same floor. "If in wheelchair, self-sufficiency once in chair".

Let's look at the terminology of, "once in chair". Once in chair relates that the resident needs assistance to get into the wheelchair, and wheelchairs are not at this time considered restraints by CMS or the MDS. Once in a wheelchair states that wheelchair use in nursing homes is in accordance with the regulations and guidelines. CMS will not release the Merry Walker from the restraint category because some residents might need assistance in getting into and out of the Merry Walker. Neither the Guidelines nor the MDS mention the fact that residents might require assistance getting into and out of a wheelchair, but yet a wheelchair is not considered a restraint. Something is definitely wrong with the inconsistency of the Guidelines and the MDS User's Manual if Merry Walker is considered a restraint if the resident cannot get out of the device by themselves, but a wheelchair, which requires more assistance to get into and out of is not considered a restraint.

The intent of the regulation F310, and Guidelines 483.25 are that the facility must ensure that a resident's abilities in Activities for Daily Living, like ambulation, do not deteriorate unless deterioration was avoidable. How can a resident reach his/her highest practicable physical, mental and psychosocial well being by being placed in a wheelchair instead of a Merry Walker, when the resident is able to walk with the assist of one person? This confirms that it is okay to use a wheelchair for a resident in a nursing home, but it is not okay to use a Merry Walker due to regulations that it is considered a restraint. Under regulations F240, Quality of Life, a facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life. Under F241, the facility must promote care for the residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality. Placing residents in wheel chairs does not promote quality of life, quality of care, or ambulation. Congress passed the OBRA Nursing Home Regulations in 1987, and the then Health Care Financing Administration wrote the Guidelines for Surveyors. The regulations that were passed by Congress are excellent, but the guidelines in the area of wheelchair use need to be changed to reflect the negative effects of wheelchair use in nursing homes, along with the use of chair alarms.

We need to discuss chair alarms as they are part and parcel to wheelchair use and why they were probably invented. Since the use of vest restraints, or commonly known as, "Posey's", were, after 1990, considered restraints, they were no longer being used to keep the elderly in wheelchairs. But the nursing homes still wanted and could keep people in wheelchairs, but without the restraint vest, the chair alarm was invented and placed on the market. The nursing homes regulations do not consider psychological restraints, such as chair alarms, as bad, and nursing homes would not be cited for their use, so soon every nursing home was using chair alarms instead of Posey belts. The chair alarm has the same affect on the end user, it keeps them in place and forbids them from standing up and walking when they have been placed in a wheelchair. Chair alarms are not considered restraints, because the person can get up from the wheelchair but the 80 decibel sound rings out, causing fear, insecurity, loss of dignity, and as a geriatric psychologist, I consider them, psychological restraints. When Jeanne Nitsch was questioned on this issue a few years ago, she stated that CMS had not looked into the issue of chair alarms, but she supposed that it would come under a quality of care issue. CMS has not addressed this issue either.

What does the use of a wheelchair do for a resident in long-term care? According to Dr. Brechtelbauer, a Professor of Family Medicine at University of South Dakota School of Medicine and Medical Director at Good Samaritan Center, Sioux Falls, South Dakota, in a 1999 study completed on wheelchairs called; "Use Among Long-Term Care Elderly", states that wheelchairs are most often thought of as assistive devices to increase mobility. They can also however promote excess dependency, causes muscular deconditioning, and be related to falls and injuries. In long-

term care settings, were the prevalence of use is usually well over 50%, the negative effects of wheelchairs can be particularily problematic and easily overlooked or not recognized. He further states that there are many reasons to use wheelchairs. The traditional reason is to increase independent mobility. Does a wheelchair increase independent mobility or does it decrease it, when in fact, could the resident walk with the assist of one prior to being placed in a wheelchair? Why wasn't the resident placed in a restorative program so that the resident could reach his/her highest practicable level of functioning? Was the least restrictive device used for this resident or was it easier just to place the resident in a wheelchair since, up until now, wheelchairs have not ever been considered restraints? Merry Walker is less restrictive than a wheelchair, yet the Merry Walker is considered a restraint if the resident cannot get out of the device without assistance. If a resident needs assistance in getting into and out of a wheelchair, that is not considered a restraint, but if the resident is independently mobile, as in walking independently in the Merry Walker, but cannot figure out how to get the front gate open, then the Merry Walker is a restraint. This interpretation of the regulations is wrong and needs to be changed, immediately.

There are additional reasons on impact of use of a wheelchair in the long term care setting, including, particularily, transport efficiency. Wheelchairs can allow staff members to transport frail residents to meals and activities quickly and safely. A restraint is never to be used for staff convenience. Is placing a resident in a wheelchair to move residents quickly and safely to activities and meals staff convenience? And a guideline deficiency?

Despite the numerous advantages of using a wheelchair, there are also many documented problems. These problems include wheelchair related falls and trips (especially during transfer attempts out of the wheelchair); collisions with objects or other persons; and the de facto use as a (generally unrecognized restraint). Why hasn't Health Care Financing Administration and now called Centers for Medicare and Medicaid recognized the simple fact? Wheelchairs are restraints! And the additional the use of chair alarms attached to the back of wheelchairs and then attached to the resident to keep the resident in a seated position, is this concept of assisting the resident to reach his/her highest practicable level of functioning?

He further states in his study that physician and therapist input is often not sought in assessing residents for wheelchairs, which results in patients using wheelchairs for invalid reasons. Also stated is that given the typical assumption that wheelchairs are used to increase self-mobility, it is striking how infrequently this type of use occurs among residents of the study facility (4% to 14%). This low frequency of use for self-mobility was also found in the l995 study by Simmons et al, where, using an entirely different methodology, the frequency of use for self-propulsion is also found to be low (4%).

In another cited study, called; "An Analysis of the Problems of Wheelchairs in Special Nursing Homes for the Elderly", states there are problems of standard type wheelchairs generally used in nursing homes. Five points are raised when consideration is given to placing a resident in wheelchair. The five points are diseases and aging of the elderly, the decreases in their abilities to position themselves, their environments, learning how to use wheelchairs, and most importantly the lack of knowledge of the professional staff about the physical problems the elderly face in using wheelchairs for their "mobility".

There are many physical and mental problems that the elderly face when they are placed in a wheelchair. Changes in body systems may include poor circulation, chronic constipation, incontinence, weak muscles, weakened bone structure , pressure sores, increased agitation, depressed appetite, increased threat of pneumonia, increased urinary infections or premature death. Changes in quality of life may include; reduced social contact, withdrawal from

surroundings, loss of autonomy, depression, increased problems with sleep patterns, increased agitation, or loss of mobility. ("Empowering Caregivers – What Are the Outcomes of Restraint Use?") Are not these same physical and mental problems the same list for elderly being placed in restraints? Yes, they are, so why has HCFA and CMS not ever looked that these problems and formulated guidelines to list wheelchairs as restraints? Why does it take a geriatric psychologist to see this error in the guidelines? Have wheelchairs just been there too long and no one has ever looked at them? In a meeting with Steve Pelovitz and others in Baltimore in March, 2002, I placed myself in a wheelchair, with foot rests. I stated that I was play-acting an eighty-something year old woman with severe arthritis in my hands and osteoarthritis in my back, but cognitively intact, and I could not lean over to get the footrests out of the way in order for me to stand up. I asked Steve how I was to do this and he stated that I was to place my feet on each side of the footrests and get up. I did this and pretended to fall slamming the wheelchair back and into the wall behind me. In this case the wheelchair was a restraint, but he would not admit that. Later in a conversation with Barry Pineles, after our March 4, 2002 meeting, Steve did admit that a wheelchair could be considered a restraint, but of course no implementation of this decision was forthwith. The guidelines are not consistent. If a resident cannot egress the Merry Walker independently, then the Merry Walker is a restraint, but if a resident needs assistance in the egress in a wheelchair, it is not considered a restraint. This is considered arbitrary and capricious.

From a study called; "Of Human Bondage- Alternatives to Restraints: Help Reduce Risk to Patients", the study states that physical restraints damage patients psychologically by causing anxiety, agitation, fear, anger, humiliation, confusion, feels of abandonment, and depression. Further restraints may contribute to incontinence, urinary retention, urinary tract infections, dehydration, and nosocomal infections, muscle wasting, weakness, poor balance and increased falls.

In a study; "Falls in Nursing Homes;" The questions is asked; "What are the most common causes of falls in nursing homes?" The answer is weakness and gait problems are the most common causes and they account for 24% of all falls in nursing homes. The study goes on to ask; 'What can be done to prevent falls in nursing homes?" The answer is physical conditioning and /or rehabilitation such as exercise to improve strength and endurance, physical therapy, gait training, or walking programs. Further the question is asked; " Are physical restraints helpful in preventing falls?" The answer is that restraints can actually contribute to fall-related injuries and deaths. Limiting freedom of movement and personal autonomy results in physical deconditioning and muscle atrophy than can cause functional decline.

According to the Guidelines restraints have potential negative outcomes that include incontinence, decreased range of motion, and decreased ability to ambulate, symptoms of withdrawal, or depression or reduced social contact. The use of the Merry Walker does not cause any of the above negative outcomes of restraint usage, so therefore Merry Walker is not a restraint.

All of the above listed symptoms force a wheelchair to be considered restraints. According to the Guidelines; "physical restraints are defined as any manual method or physical or mechanical device, material, or equipment attached to the resident's body that the individual resident cannot remove easily which restricts freedom of movement or normal access to one's body". A wheelchair is a mechanical device that the resident cannot remove easily and restricts freedom of movement.

The Guidelines further state that; "Discipline is defined as any action taken by the facility for the purpose of punishing or penalizing residents". Once a resident is placed in a wheelchair, the resident is being penalized by not allowing the resident to reach his/her highest practicable well-being, and once a chair alarm is added to the back of the wheelchair, the resident is being punished psychologically and auditorally every time the resident wishes to stand up and walk by a loud 80

decibel alarm that sounds off to keep the resident in a seated position. I have been told my numerous physical therapists working with the elderly that is takes about three weeks or less, after placing a resident in a wheelchair, without daily functional restorative care, and the resident never walks again. So the nursing home staff receives a new resident, finds on the MDS resident assessment that the resident is unable to walk unassisted and places the resident in a wheelchair. When the resident decides to start trying to get up and walk, a chair alarm is placed on the back of the resident and attached to the wheelchair and when the resident tries to stand up, the alarm rings at 80 decibels and the nursing staff person comes at once and tells the resident to sit down. After three weeks, the resident is no longer able to stand up and walk and the facility is not cited for least restrictive device and the resident never walks again. If the resident had been placed in the Merry Walker the resident would still be walking and not suffering the physical and mental downward consequences of restraints use, yet the nursing home is not cited for restraint use in this case.

The Guidelines also define "Convenience as any action taken by the facility to control resident behavior or maintain residents with a lesser amount of effort by the facility and not in the residents' best interest." What best interests are served to the resident by placing the resident in a wheelchair?

In a letter written on September 11, 2001, by Steve Pelovitz, Director of Survey and Certification Group, CMS, he states that, "CMS instructs that the evaluator focus on the effect of the device on the individual resident." The effect that the Merry Walker has on the resident is independent ambulation. The effect a wheelchair has on a resident is all the aforementioned negative affects that restraints have on residents.

The Guidelines have caused major decreases in quality of care, and if the wheelchair is declared a restraint, and the Merry Walker removed from the category of restraints, all kinds of positive outcomes would be measured under quality of care. The residents would attain their highest practicable physical, mental and psychosocial well being for which Congress intended when the OBRA Regulations were passed in 1987.

Other regulations in OBRA of 1987 would also be followed such as the facility promotes the quality of life of each resident, the facility ensures dignity of each resident, the facility develops and implements written policies and procedures that prohibit mistreatment, neglect, and abuse of residents, the facility ensures comprehensive assessment of each resident, the facility develops comprehensive care plans for each resident that include measurable objectives and time tables to meet each resident's medical, nursing and medical needs, the facility ensures that each resident received and the facility provided the necessary care and served to attain or maintain the highest practicable physical, mental, and psychosocial well-being in accordance with the comprehensive plan of care, the resident's abilities in activities for daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that diminution was unavoidable, the facility has in place and follows procedures to ensure that residents do not develop pressure sores unless resident's clinical condition demonstrates that they were avoidable, the resident who is incontinent of bladder receives appropriate treatment and service to prevent urinary tract infections and to restore as much normal bladder function as possible, a resident with limited range of motion receives appropriate treatment and services to increase range of motion and/ or to prevent further decrease in range of motion, each resident maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible. With the Merry Walker out of the restraint category and the wheelchair placed in the restraint category, all this would be possible.

In the MDS under Section G, Physical Functioning and Structural Problems, we cite examples of set-up help. Since CMS is very concerned about resident transfers, it mentions giving the resident a transfer board or locking the brakes on a wheelchair to safe transfer, as assistance given. For locomotion, it mentions walking, as giving a resident a walker or a cane, and under wheeling, under locomotion, unlocking the brakes on the wheelchair or adjusting foot pedals to facilitate foot motion while wheeling. Under HCFA F85-F87 in a HCFA -672 (10/98) in the second paragraph, it states that many facilities routinely provide "set-up" assistance to all residents, such as handing the equipment (e.g. sliding board) to the resident. If this is a case and is the only assistance required is to lock the brakes and adjust the footrests, the MDS counts the resident as independent. If the resident is seated in a wheelchair, but needs assistance to set the brakes, place the footrests correctly, get in and out of a wheelchair with assistance, the wheelchair is not a restraint under the MDS. If the resident cannot move a wheelchair without assistance, the wheelchair is still not a restraint. Merry Walker was placed under "chair prevents rising" because the resident does not have freedom of movement when the resident is unable to open and close the front gate. The gate was designed to hold securely as a safety measure, not to restrict the resident from free movement. The resident, being assisted into and out of a wheelchair is more restrictive to the resident than the Merry Walker.

Under F103 of the same regulatory document, ambulation with assistance or assistive devices...the number of residents who require oversight, cueing, physical assistance or who use a cane, walker, crutch. Since Merry Walker is considered a walker, Merry Walker does not fit into the restraint category, and the wheelchair does.

Under the l999 publication of the Kendal Corporation, called "Untie the Elderly"; Legal Aspects of Physical restraint Use in Nursing Homes, Part 1"; under bed side rails may qualify as restraints, it states that when side rails used on a bed of a completely immobile resident, while not necessary, are not considered restraints because that person is not trying to leave the bed. Under this definition, when a resident is placed in the Merry Walker and the resident does not want to get out of the Merry Walker, then the Merry Walker should not be placed under a restraint category. Residents want to walk as walking is a natural human function and we are supposed to walk for normal body functions to occur.

Let's now look at the negative effect of wheelchair use for the elderly. Cindy Hake, senior policy analyst for the Centers for Medicare and Medicaid Services spoke at the American Association of Nurse Assessment Coordinators at their conference in Anaheim, California in l999. She stated that prevention of pressure sores is a big challenge that nursing homes must meet. Research tells us that most pressure sores are avoidable, most, Hake said. In fact, CMS database reveals that 9.8% of residents in nursing homes have at least one stage two or higher pressure sore. That means that on any given day, about 170,000 residents in facilities across the country have a pressure sore that could have been avoided, she said. Why do these 17,000 residents have pressure ulcers? The answer is because of wheelchair use and poor restorative care. The nursing home staff are not following the regulations and the guidelines and are not being encouraged to banish the use of wheelchairs. Use of wheelchairs are the main cause of pressure ulcers in nursing home residents. Countless dollars are spent yearly on pressure release cushions for wheelchairs. Why, because wheelchairs cause pressure ulcers. Make wheelchairs restraints and there will be a major decline in pressure ulcers.

In a study completed by Brienza, et. al., under the University of Pennsylvania, 2001, called; "The Relationships Between Pressure Ulcer Incidence and Buttock-Seat Cushion Interface Pressure in at-Rick Elderly Wheelchair Users." The results of the study indicate that higher interface

pressure measurements are associated with a higher incidence of seating-induced pressure sores. The onset of pressure ulcers should never, never be faced by nursing home residents.

In an article titled; "Decubitus Ulcer Sites in Wheelchair-Bound Individuals; Common Locations for the Development of Decubitus Ulcers in Wheelchair-Bound Individuals"; states the following. A decubitus ulcer is primarily formed from the pressure and weight of one's own body pressing the skin and other tissues between the person's bones and a firm surface, such as the seat of a wheelchair.....the most common site for the development of a decubitus ulcer is upon the coccyx or buttock when someone sits for extended periods of time with changing their position.

Decubitus ulcers are not necessary. They are all preventable with proper nutrition and mobility. Since Cindy Hake reported that in 1999 there were 170,000 nursing home residents with pressure ulcers that cost someone, either Medicare or another medical insurance payer, $1.3 billion dollars per year. Pressure ulcers cost, depending on the stage of the sore, from level one, redness to the affected area, to level five, which has involved the area to much that the pressure ulcer is down to the bone. Pressure ulcers cost up to $40,000 per ulcer to medicate and possibly heal, with many never healing. Why do we have the prevalence of pressure ulcers even allowed in hospitals and nursing homes? If wheelchairs were considered restraints, the prevalence of pressure ulcers would decrease dramatically because the nursing home facility staff would be forced to keep the residents up and walking and following the regulations set forth in 1987. In the twelve years since Merry Walker was invented, we have never received reports of any incidences of pressure ulcers. We have a pressure ulcer upgraded cushion that can be added to a Merry Walker and we never get any requests for the upgraded seat. No one walking in the Merry Walker gets pressure ulcers, because their nutritional intake is high and they are walking. Movement and nutrition are the reasons pressure ulcers do not form. If these 170,000 nursing homes residents had received the benefits of a Merry Walker, only $88,000,000 would have been spend on their care, and $1.2 billion would be saved, along with the pain and suffering endured by the resident.

Residents usually are placed in wheelchairs because the resident has fallen, with or without injury. In fact over 50% of residents fall in nursing homes each year, which correlates to the amount of residents in wheelchairs, between 50% and 65% in nursing homes. The total cost of fall injuries, according to an article called:" The Costs of Fall Injuries Among Older Adults;" states that the direct costs of all fall injuries for people over 65 and older in 1994 was $20.2 billion and by 2020 the cost will be $32.4 billion. In an article called; "Fall Prevention in the Skilled Nursing Facility"; states that Rubenstein et. al. (2000) found a reduction in a three month fall rate, when adjusted for activity level, in chronically-impaired fall prone elderly who participated in exercise programs focused on increasing strength, endurance and improving mobility and balance. Further studies suggest that reduction of mobility through restraint is more harmful than beneficial and should be avoided.

In another article, titled; "Falls in Nursing Homes"; states that weakness and gait problems are the most common causes and further state that physical conditioning and/or rehabilitation such as exercise to improve strength and endurance, physical therapy, gait training or walking programs.

An MDS Quality Indicator Report, for January/ March 2000

Q101: Incidence of New Fractures: All the States are listed and when added up and divided shows the incidence of new fractures to be on average 1.75 % or 31,500 over three months and 378,000 for the year.

Q102: Prevalence of Falls: All the states are listed when added up and divided shows the prevalence of falls to be 15.66% or 28,188 and the total for the year is 338,256. Added together the figure is 716,256 and treatment costs for those new fractures - $151.2 billion dollars.

The Merry Walker could have prevented most of those falls, if the resident had been placed in the Merry Walker prior to the fall.

What is needed and has been required of nursing homes since the passage of the OBRA Regulations in 1987 is for the nursing homes to read the regulations and then follow them and have the surveyors adhere to the regulations and cite the facilities who are not in compliance with the regulations. CMS needs to changes some of the guidelines to make it completely clear on what the regulations are stating and what was meant by the regulation when they were passed. Under the regulation F272, Resident Assessment: the facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity, physical and mental functional status, special treatments and procedures (specialized rehabilitation services), rehabilitation potential, which is defined as the ability to improve independence in functional status through restorative care programs. Let's look at rehabilitation potential as it exists today in nursing homes. Since Prospective Payment System was put into place over three years ago, and a resident moves into the facility from a hospital stay of three days or more and is place din a Medicare bed. Physical therapists will receive $1500.00 for caring for that resident over the next twenty days, along with occupational and speech therapists sharing another $1500.00. After the twenty allowable days, the resident is now moved into the long term care section of the facility. Now the resident is recommended for restorative care. If the resident is mobile with one assist, the resident is placed in a wheelchair, but is allowed to walk to and from the dining room on days when staff is available. Most facilities do have this type of restorative program, but it consists on walking a resident back and forth from his/her room to the dining room and of course back and forth to the bathroom. This limited exercise program is not enough. Most facilities offer wheelchair exercises once or twice a week. All of this is not enough to keep a resident ambulatory.

The definition of rehabilitation is defined as the restoration of an individual to the fullest potential consistent with his or her impairment and environmental limitations, has become extremely important as the elderly population in the United States has continued to increase in numbers.

There is a term that was developed at Tufts University in Boston called sarcopenia. Sarcopenia is simply loss of muscle mass, but can be reversed and slowed significantly by strength training exercise. Irwin Rosenberg, states that not only does loss of muscle mass lead to frailty and helplessness, it also contributes significantly to life-threatening bone breaks. He further states that the weakness that results in imbalance that results in falling is a very important element, along with low bone mass, in the high incidence of hip fractures.

Now we will look at osteoporosis, aging changes in bones. According to the Illustrated Health Encyclopedia, bone mass or density is lost, especially in women after menopause. (Our elderly women today, which make up most of the population in nursing homes today have never been prescribed to take hormone replacement therapy nor supplemental calcium tablets.) Because of this their bones have become more brittle and broken easily. Movement slows and may become limited. The walking pattern becomes slower and shorter. Walking becomes unsteady and there is less arm swinging. Fatigue occurs more readily, and overall energy may be reduced. The bones lose calcium and other minerals. Loss of muscle mass reduces strength. Injury risk is greater because of falls related to gait changes, instability and loss of balance. Inactive or immobile elderly people do experience weakness from lack of exercise. Muscle contractions or inability to move a muscle may occur in those unable to move voluntarily or to have their muscles stretched through exercise. Exercise is one of the best ways to slow or prevent problems with the muscles, joints and bones. A

moderate exercise program can maintain strength and flexibility. Exercise helps the bones to remain strong.

From the Family Resource Center; " Strategies for Improving Resident Mobility", states that ca common challenge for residents in nursing homes is immobility, which can result in a variety of physical complications and cause feelings of isolation, anxiety and depression. While many people assume that immobility I a natural consequence of old age, research studies have shown that the elderly have a much greater potential for mobility than previously believed. Several of the physical changes associated with the aging process can impair a resident's ability to move independently. Decreased efficiency of the cardiovascular and respiratory systems can lead to movement difficulty and weakness. Many elderly individuals have diminished muscle tone, often reflecting the result of sedentary lifestyle. Vision and hearing impairments can make navigation around one's environment challenging. There is also a higher prevalence of chronic illnesses, painful condition, and medication usage during the later years which can dramatically affect mobility and independence. Some of the common age-related causes of impaired movement include arthritis, osteoporosis, stroke and Parkinson's disease.

The report goes on the say that many elderly enter today's nursing homes in dire physical condition. In l995 the National Institute on Aging released some revealing statistics about elderly beyond age of 75: 40% cannot walk two blocks, 32% cannot climb ten steps, 7% cannot walk across a small room, and 50% of older people who fracture hips never walk independently again and many die from the complications of hip surgery. As these statistics reveal, residents in nursing homes face many serious challenges with mobility that affect their autonomy, control and well being. Maintaining mobility has profound effect on the physical and psychological well-being of the elderly. (The nursing home, according to the OBRA regulations is to provide services for the resident to attain or maintain the resident's highest practicable physical, mental and psychological well-being) Disuse or immobility may result in complication in almost every body organ system, which may lead to further disability and illness. Some common effects of immobility include:

- **Increased stress on the heart**
- **Orthostatic hypotension**
- **Pooling of secretions in the lungs**
- **Demineralization and loss of bone**
- **Muscle atrophy and weakness**
- **Pressure ulcers**
- **Sensory deprivation**
- **Urinary complications**
- **Feelings of helplessness, depression, anxiety**

NASA has been studying the aging process in testing the effects of weightlessness in space. They state that gravity is not just a force, it's also a signal- a signal that tells the body how to act. For one thing, it tells muscles and bones how strong they must be. The muscles used to fight gravity- like those in the calves and spine, which maintain posture—can lose around 20% of their mass if you don't' use them. Muscles mass can vanish at a rate as high as 5% a week. Zero –G living mimics closely the effects of old age. Like astronauts, the elderly fight gravity less. They're more sedentary, which triggers the loop of muscle atrophy, bone atrophy and lower blood volume. So placing a resident in a wheelchair causes 5% of their muscle mass to decrease weekly and since they are very weak to begin with, in three weeks a 15% loss becomes very significant, adding to further and further decline in physical function and soon they never walk again.

Dr. William J. Evans, Noll Physiological Research Center and professor of nutrition and applied physiology at Pennsylvania State University, started an exercise study with the idea that what works well in young people should work well with the elderly. In his study; "Muscles: Use Them or Lose them", states that among all the sophisticated studies, exercise stands out as a simple effective prescription that is appropriate for everybody.

Dr. Evans, in a study cited as; " Exercise Counter Measures to Age and Microgravity"; states that we have demonstrated that resistance exercise results in large increases in muscle size and strength even in men and women as old as 100 years old.

Dr. Evans states in another study that further states that nursing homes are filled with elderly people who are institutionalized not because of any disease or cognitive impairment, but because of muscle weakness. Wheelchair use has made a significant contribution to this ambulation impairment.

In another study by Robert Mazzeo, professor of exercise physiology at the University of Colorado, "Making Muscle a thing of the Present"; he states that the major health risks for the frail elderly are immobility, falls and fractures, which are all related to muscle weakness. Strength training and balance exercises can help older adults build muscle strength and improve function so they can safely walk and do other aerobic activities. Numerous studies demonstrate that resistance exercises can help frail elderly people in their eighties and nineties improve their strength to the point where many regain the ability to walk and perform other tasks without assistance.

Joseph A. Buckwalter, MD et. al. completed a study called; " Loss of Conditioning and Mobility"; states that weakness, stiffness and pain after physical activity and chronic fatigue and among the most common complaints of middle-aged and older individuals and are leading causes of progressive loss of mobility. These complaints should not be dismissed as the inevitable consequences of aging, but should lead to a careful evaluation and development of a treatment plan. He further states that for most elderly persons, a regular exercise program that increases aerobic capacity, flexibility, and strength is the intervention with the greatest potential for improving mobility, as well as increasing endurance and strength and helping maintain bone mass. Aerobic exercise for people who have been sedentary may include a walking program. The MDS does not address this issue as completely and thoroughly as it should.

There are so many studies on this subject that I could go on and on citing them, but the main point that is made from all the studies cited is that elderly lose muscle strength either through disease manifestations or just plain physical deterioration. Nursing homes are mandated to assess for mobility through their varying professional modalities, but after the assessment is completed, the resident ends up in a wheelchair for staff convenience or more importantly, ends up in a wheelchair due to the fact the CMS does not realize the important of exercise and ambulation and has never declared that a wheelchair is a restraint. Once that is done, and all the evidence points to the fact that wheelchairs are restraints, if the resident cannot set the brakes and get up and out of the wheelchair independently, the results will show that the staff of the facilities will be forced to follow the federal regulations to not only follow the minimum standards, but also actually cause improvements to the quality of care outcomes for all the residents of nursing homes. Allowing the residents to walk safely and restraint free in the Merry Walker or other devices will immediately increase quality outcomes in nursing homes. The CMS Guidelines need to be revised to reflect new measures and new devices that have been developed to improve the quality of life in nursing home residents. As many medical product developers are watching and listening today to this hearing, the future of quality care in long term care is at stake. They have been asking themselves for years why should we develop new products, if the federal government is not going to allow them to be

used for the purpose intended? I should not have had to spend a year and a half doing research on this subject and fighting with CMS to let a device such as the Merry Walker be freed from the restraint category. CMS should have taken measures a year a half ago when the subject was raised and completed their own research on the subject of elderly rehabilitation and come to the same conclusion as so many other have done. The nursing homes in this country should be a place to live out one's years with dignity instead of being restrained to a bed or a wheelchair with an alarm and the Centers for Medicare and Medicaid have done their best to make the United States one of the worst countries in the world for quality long term care for our elderly.

Since our 1.8 million elderly living in nursing homes today in this country have been placed in the facility due to deteriorating health status either from the onset of an Alzheimer's or related dementia or from frequent falls in the home or general physical weakness, who is the professional staff member that is completing the MDS Section G, Physical Functioning and Structural Problems? Since the Prospective Payment System removed most physical and occupational therapist from the long term care sections of the nursing homes three years ago, who is now professionally qualified to measure and assess the residents for:

- **ADL Self Performance**
- **Bed Mobility**
- **Walk in Room**
- **Walking Corridor**
- **Locomotion Off Unit**
- **Dressing**
- **Eating**
- **Toilet Use**
- **Personal Hygiene**
- **Bathing**
- **Test for Balance**
- **Functional Limitations in Range of Motion**
- **Modes of Locomotion**
- **Modes of Transfer**
- **Task Segmentation**
- **ADL Functional Rehabilitation Potential**
- **Change in ADL Function**

What professional staff person in the facility is making these life choices for the resident? Nursing? Has nursing been trained in physical therapy, occupational therapy and speech therapy to assess the residents correctly or is staff just filling in paper work? How is the lack of qualified professional staff making these judgments affecting the physical, mental and psychosocial of the 1.8 million residents of long term care? It must be mentioned that most nurses retained in nursing homes today may or may not have the training that should be required in rehabilitation prior to accepting their present position. Since NURSING SHORTAGE is a great topic today and being blamed for everything wrong in nursing homes today, maybe, just maybe, we should look into restoring occupational and physical therapy, along with speech therapy, who alone can address communication and eating skills, back into the long term care sections of nursing homes to complete the Physical Functioning and Structural Problems section of the MDS. If there is such a nursing shortage today, and the nurses who are in the facilities working their hardest, is it possible that nurses do not have the time to complete the MDS as it was intended? Is it just possible that

this section is not been completed correctly due to the shortage of nurses? And who is suffering from this? The 1.8 million elderly living in our nursing homes today are the ones that are losing out with this system.

Dr. Mary Tinnetti, Professor of Internal Medicine, Yale University School of Medicine, has completed many studies on falls in the elderly, fall prevention methods and has been widely published. She is one of the best known researchers in the geriatric and internal medicine fields today and has criticized the disease oriented approach to assessment of mobility problems. Tinetti prefers a performance –oriented approach, asserting that falling is an entity in its own right, most commonly due to the accumulated effect of multiple chronic disabilities, and that it may be preventable if the causative factors are recognized in individual patients. Tinetti developed a Performance-Oriented Assessment of Mobility that assesses for gait and balance in 1986. There are also many other assessments that can be used in conjunction with the POAM, such as the Functional Balance Test, Balance Self-Perceptions Test, Dynamic Gait Index, Three-Minute Walk Test, and Fall Risk assessment. Since these tests are not used as part of the MDS, and should be, to give the therapist an accurate assessment of exactly the measures of the resident performance. Therefore these assessments of gait and balance will give the nursing home staff a natural step by step procedure to place the resident in obtainable and measurable goals and objectives of the resident care plan if the resident requires restorative care in order for the resident to reach the highest potential in physical, mental and psychosocial well-being, according to the regulations. Why hasn't the Center for Medicare and Medicaid Services incorporated study tested materials and devices into their system? The present test for balance in the MDS does not test the resident thoroughly enough, nor does it take into account any residents with severe cognition diagnoses that walking is an involuntary function, but testing in this matter may not reveal the true ability to ambulate. The present evaluation does not allow the assessment results to allow concrete decisions on future goals and objectives for the resident in the resident care plan. Therefore since the balance test does not thoroughly measure the resident's status completely, restorative care cannot be measured and then placed in the resident's care plan in this area due to the weakness of the measuring instrument and the staff qualifications for measuring these areas. How can a resident be expected to reach his/her highest physical potential when the initial assessment is not measuring for this?

Can residents in long term care gain benefits from rehabilitation and subsequent removal from wheelchairs? There are many, many medical studies that have focused their research on this very topic.

1. In the Journal of the American Medical Association, a study was cited titled; "Physical Activity and Mortality in Postmenopausal Women," found in the conclusion of their study that these results demonstrate a graded, inverse association between physical activity and all-cause mortality in postmenopausal women. These finding strengthen the confidence that population recommendations to engage in regular physical exercise are applicable to postmenopausal women.
2. In Merck's Manual of Diagnosis and Therapy states that exercise (range of motion, isometric, isotonic, isokinetic, postural, strengthening) maintain healthy cartilage and range of motion and develops stress-absorbing tendons and muscles. Daily stretching exercises are of utmost importance. Immobilization for relatively short periods can accelerate and worsen the clinical course. Arrest

and occasionally reversal of hip and knee OA can occur using well-planned exercise as therapy.

3. **"Combating the Effects of Immobility", McNeill and Schanne, state that nursing measures that mobilize patients and promote their independence in activities for daily living can prevent muscular deconditioning and skin complication. Many of these interventions, such as leg exercises, benefit several systems at the same time. For example weight bearing on longitudinal bones not only helps to 6promote musculoskeletal and cardiovascular tine, but also combats the loss of calcium and phosphorous from bone. They further state that patients admitted to hospitals, intermediate and long term care facilities need astute nursing assessments and early interventions to prevent permanent disabilities and potential life-threatening complications that can result from bed rest and immobility. Nurses need to initiate consistent interventions to prevent psychological and physical deconditioning, progressive dependence and deterioration and possible death. We can do this by keeping our patients moving.**
4. **From the Centers of Disease Control and Prevention, an article on Older Adults states the benefits of physical activity:**
    - **Helps maintain the ability to live independently and reduces the risk of falling and fracturing bones.**
    - **Reduces the risk of dying from coronary heart disease and developing high blood pressure, colon cancer and diabetes.**
    - **Can help reduce blood pressure in some people with hypertension.**
    - **Helps people with chronic, disabling conditions improve their stamina and muscle strength.**
    - **Reduces symptoms of anxiety and depression and fosters improvements in mood and feelings of well-being.**
    - **Help maintain healthy bones, muscles and joints.**
    - **Helps control joint swelling and pain associated with arthritis**
5. **"Effect of Multidemensional Exercises on Balance, Mobility, and Fall Risk in Community-Dwelling Older Adults"; Shumway-Cook, Gruber, Baldwin, Liao, found that our results show that a multifaceted exercise program improves balance and mobility function in community dwelling older adults with a history of falls. In addition, adherence to a structured exercise program reduces the risk for falls among older adults.**
6. **"Exercise for the Elderly;" Elif Erim, MD, states that the Surgeon Generals' Office, the National Institutes of Health, the Center for Disease Control and the American College of Sports Medicine all agree that sedentary people who wish to become more physically active need only 30 minutes of moderately intensive physical activity during the course of a day to stay active and remain active.**
7. **"Exercise Parameters for the Elderly"; Beth Lyndon-Griffith, School of Occupation therapy and Physical therapy, University of Puget Sound, Tacoma, Washington, states that in conclusion of the study she found exercise can be the key that allows elderly people to be able to lead independent and productive lives. For those who are less independent, exercise can enable them to slow down physical deterioration or maintain a more consistent state of performance.**

Exercising elderly need to be assessed and made aware of their physiologic limitation and need to be taught the warning signs of overexertion. Depending on their individual goals, most elderly people should be able to achieve a higher level of fitness which should allow them to maintain and enjoy increased function abilities.

8. **"Comparison of Past Versus Recent Physical Activity in the Prevention of Premature Death and Coronary Artery Disease"; American Heart Journal, states tin the conclusion in their study that the reduction in overall mortality rates is more associated with recent activity that distant activity. These results suggest that for sedentary patients, it may never be too late to begin exercising.**
9. **"Effects of Exercise on Falls in Elderly Patients, A Preplanned Meta-Analysis of the FICSIT Trials. Frailty and Injuries: Cooperative Studies of Intervention Techniques"; JAMA. Objective: to determine if short-term exercises reduces falls and fall-related injuries in the elderly. Conclusion: Treatments, including exercise for elderly adults reduce the risk of falls.**
10. **The Real Age Diet, Michael F. Roizen, MD states in his book, that it's never to late to start. My favorite success stories involve two studies of retired citizens. Visualize a nursing home with people in wheelchairs and walkers. Then visualize these same people being able to abandon their wheelchairs. It's almost a miracle cure at the hand of a faith healing preacher. But this study was done by scientists, and results happened not in one person but in half of all the residents who were dependent on wheelchairs in a nursing home. It happened because they started to do resistance exercises. Pretty amazing, but that's what happened. In the first study (the average age was eighty-three), more than half of the nursing home residents who were in wheelchairs were able to become more functional and independent after just sixteen weeks of strength training exercises.**
11. **"Relation of Rehabilitation Intervention to Functional Outcome in Acute and Subacute Settings;" Allen W. Heinemann, PhD, Northwestern University. One interesting idea that emerged from this study is that the extent of functional improvement is greatest when therapeutic goals and activities are only slightly greater that the current level of patient function, barriers to rehabilitation are minimal and comorbidity is absent.**
12. **"The Changing Approach to Falls in the Elderly"; by Kenneth K. Steinweg, MD, states that the annual incidence of falls is approximately 30 per cent in persons over the age of 65 years. The risk of falls is greater in older persons, with the annual incidence increasing to 50 per cent in those over age 80 .....Most falls in the elderly are caused by complex interaction of intrinsic and extrinsic factors. A thorough history is essential to identifying the intrinsic and extrinsic factors involved. Approximately one half of the falls in the elderly can be attributed to accidents and extrinsic factors such as slippery floors, and the remainder from intrinsic causes such as lower extremity weakness, gait disorders, effects of medications or acute illness. Extrinsic and intrinsic factors that are identified may be amenable to one of three management approaches: treating acute or reversible deficits, reducing the cumulative burdens of deficits, or suing adaptive devices for reversible effects. A careful and focused evaluation**

can identify factors that can be corrected or therapeutic interventions that will lesson the risk of a subsequent fall.

In summary, this presentation has proven many facts and realities that must be presently faced by Centers for Medicare and Medicaid to improve the care of 1.8 million elderly who depend on this agency for the quality of care regulated by Congress in 1987; which, twelve years after enactment is in great need of quality improvement. I have shown that the regulations need to be enforced. The guidelines need to be clarified to follow the intent of the regulations, that of improving quality of care for the nations 1.8 million American elderly who depend on CMS to ensure quality of care. Basically, the MDS needs to change its policy and remove the Merry Walker and any description thereof, as a chair that prevents rising, under restraints, and the guidelines for wheelchair use need to be altered to consider wheelchairs for what they are...restraints. In essence wheelchairs hurt the elderly by not allowing restorative care to occur, increasing falls in nursing homes to over 50%, and pressure ulcer involvement showing major increases and creating more dependent nursing home residents than prior to the enactment of the regulations and subsequent guidelines. We have shown that exercise is good, that the Merry Walker provides that necessary exercise, and wheelchairs are bad because up to 1 million elderly people are using them in nursing homes which are not receiving deficiencies. Wheelchairs cause unnecessary deterioration for the elderly and by using them cost billions of extra dollars in unnecessary expenses. In conclusion, allow Merry Walker to be removed from the restraint category and place wheelchairs where they rightfully need to be, under chair that prevent rising, as that is what they provide for the resident. The Centers for Medicare and Medicaid need to realize that new information on the underlying causes of and risk factors for diseases and disabilities are helping researchers develop intervention to delay onset, slow progression and reduce the severity of disease and disability. New products are and have been developed to address the issues of age onset diseases and disabilities. Centers for Medicare and Medicaid need to educate the policy writers of the innovative developments and not randomly forbid use of these products without complete knowledge of the product, which without the negative regard from CMS might actually assist the population they were designed to serve.

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Department of Health and Human Services
Regulatory Reform Initiative

Name: Sharon Linet

Organization: Ashlar of Newtown

Regulatc
Reform H

How user interacts with the healthcare system:	
description of involved regulation:	F221 Restraints
statement of problem:	While I completely agree that people should not be restrained, the burden of over-interpretation of this regulation is a problem. For example, coding a Merry Walker as a restraint is ridiculous. A Merry Walker allows a person to walk freely who otherwise would require supervision and standby assist. In the MDS 2.0 Question and Answers document of 9/13/02, it states that this device could restrict someone from entering areas with stairs, transferring to another chair, etc. A person who needs this much supervision shouldn't be able to enter areas with stairs and should be supervised with transfers!!! In addition, the Q & A document also says to code a Merry Walker as an ambulation device. How can something that assists ambulation also be a restraint! The fact is that problems with gait, balance and proprioception are a fact of life with an elderly population. With these problems come the problem of HIGH fall risk. The restraint regs. are so overinterpreted it makes providing safe ambulation very difficult. The fact is that while staff could be walking these people, they are burried in documentation proving that they are NOT restraining. The definition of a restraint should be that it is a device used to prevent a person from purposeful movement. If puposeful movement is not prevented then there is no restraint. I have a lady in the end stages of dementia who needs a Geri Chair with the tray up to keep her from sliding out of the chair to the floor. Just because she CAN slide doesn't mean that she wants to or that she should be sliding to the floor. She couldn't get up and walk if her life depended on it. She moves her arms and legs about in non-purposeful movements. This chair is not a restraint. It keeps her sitting up in an anatomically correct position which facilitates eating etc. We are coding it as a restraint because of the definition. The RAP note explains that the chair is for positioning. My concern is now with the Nursing Home Compare website. We have a debilitated population. Many of our people require positioning devices to keep them in anatomically correct positions. We code them as restraints. Our facility looks HORRIBLE in the restraint category. An uneducated consumer looks at that and they don't see the rap notes. I think this is very unfair to Nursing Homes.

potential solutions:	Change the definition of restraint. A device that prevents purposeful movement.
ways solutions maintain the original intent of regulation:	When purposeful movement is prevented it is a restraint and the orgininal intent was to stop LTC providers from tying up the elderly for convenience. This still holds true. If you are preventing purposeful movement then you are restraining. If these devices are used for positioning and are not considered restraints then the burden is reduced because there would be 1. less devices coded as restraints 2. less documention needed.
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facsimile transmittal

To: Mary Harrison Fax: 8156783399
From: Mary Walker Trans Staff Admin Date: 11/7/01
Re: Mary Walker Pages:
CC:

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Notes: MDS code change for Mary Walker as requested.

Nov. 8, 2001

To whom it may concern:

This letter is in regard to the usage of "merrywalkers" in our skilled nursing facility in Encinitas California. Our facility has an unit that is specialized for the care of residents with Alzhemiers and or Dementia. This unit currently has 10 residents that utilize the "merrywalker" daily.

The benefits of using the "merrywalker" are many. The residents that maintain their ability to walk by holding onto the front bar and being able to sit for rest periods at will while in the "merrywalker" have better muscle tone in their legs which helps promote proper circulation. Their leg edema is often reduced by the fact that they are ambulating. The fact that they are able to ambulate at will also lowers their risk for pressure sores. Currently none of the residents who use the "merrywalker" have any alteration in their skin integrity.

The residents who use the "merrywalkers" are able to move about their unit mostly independently. They are able to socialize with one another freely. They are able to walk themselves to the activities. The walkers help them maintain their independence.

The definitions under section *P* of the mds requires that the "merrywalker" be coded as a chair that prevents rising. We are coding it as such and also coding it as a walker under the physical functioning section G-5 (modes of locomotion).

As a facility with an specialized Azlhemiers unit we see the benefits of using these walkers when appropriate.

Sincerely,

Frances Shay
Administrator

BEVERLY
HEALTHCARE

September 6, 2001

Mary Harroun
Merry Walker Corporation
11475 Commercial Dr
Richmond, IL 60071

Dear Ms. Harroun;

As per our conversation yes we have had occurrences of citation ~~for the use~~ of Merry Walkers in our facilities. The problem appears that the states interpret the use of this device as one that of a "chair that prevents rising." We have always considered this type of device as an enabler, assisting the resident with their mobility and independence.

- If the resident can open the front gate of the device, it does not meet the definition of "Physical Restraint" in that it does not restrict freedom of movement, or access to ones body, and can easily be removed.
- It is considered an enabler or justified restraint if the end user is unable to open and close the front gate. The RAP process is then used to describe the nature of the condition, factors that need consideration, and complications and risk factors.

Best regards,

John Ferguson
Clinical Specialist
Professional Services, Beverly Healthcare

One Thousand Beverly Way
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[redacted]

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August 31, 2001

Mary Harroun
% Merry Walker Corporation
11475 Commercial, Suite #9
Richmond, IL 600071

Dear Mary:

I am writing this letter as a follow-up to our phone conversation regarding merry walkers. In the MDS Coordinator workshops, which we teach at our corporate office, we stress that when coding the MDS they should always go by what is in the Resident Assessment Instrument (RAI) manual. According to the RAI manual, merry walker are considered a chair that prevents rising, so this is how we tell our staff in our facilities to code merry walkers. Although I agree with you that merry walkers do not prevent a resident from rising, it is our responsibility to carry out what CMS or HCFA requires.

If you have further questions, please contact me at (605) 362-3279.

Sincerely,

Kris Ponto

Kris Ponto, RNC
Nurse Consultant

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October 9, 2001

Mary M. Harroun, MS, LNHA
President
Merry Walker Corporation
11475 Commercial Dr.
Richmond, IL 60071

Dear Ms. Harroun,

We have been made aware that the HCFA guidelines classify the Merry Walker as a restraint device. We would like to register our disagreement with this position. As a company that sells the Merry Walker, we do not advertise or promote this product as a restraint device, but rather we market it as a mobility product.

The Merry Walker is a great aid for people with limited independent ambulatory capability in assisting them reach their highest level of independence and functionality. Please pass along our request to HCFA that the determination, which qualifies these products as a restraint device, be changed.

Sincerely,

Paul Bartu
Group Product Manager
Sammons Preston

October 10, 2001

Secretary Tommy G. Thompson
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Thompson:

I am writing in regards to the Merry Walker©, as mentioned in the Minimum Data Set (MDS2.0) for Nursing Home Providers as described in the questions and answers section on the Centers for Medicare & Medicaid website.

As a professional with over twenty years experience in the field of aging, my understanding is that the Merry Walker© is a walker/chair combination that may be helpful with individuals with dementia. It is also my understanding that it is not a chair that prevents rising.

Thank you very much.

Sincerely,

Fran Hankin

Fran Hankin
Associate Director, Education Services
Alzheimer's Association
4709 Golf Rd., Suite 1015
Skokie, IL 60076

The Nursing Service Group, Inc.

P. O. Box 32
Barrington, Illinois 60011
Telephone (847) 382-1629 Fax (847) 382-1641

September 17, 2001

Merry Walker Corporation
11475 Commercial Drive
Richmond, Illinois 60071

Re: Merry Walker Products

Dear Ms. Harroun:

Thank you so very much for developing wonderful products to assist residents to maintain their respect, dignity and ambulation ability. Ambulation is such an important activity to prevent medical complications. These medical complications not only increase unnecessary and outrageous Medicare and Medicaid costs but pain and suffering to these dependent and frail residents.

It has come to my attention, the use of the Merry Walkers are often not used due to the nursing tool, Minimum Data Set, for long-term care facilities. As long term care nurse and educator, Board Certified in Gerontology and over seventeen years of experience, it is my professional opinion the Merry Walker products maintain resident independence, quality of life and reduce these unnecessary medical complications. The lack of use of the Merry Walker as an essential assistive mobility device results in many residents becoming incontinent, developing costly and painful pressure sores, limb contractures, constipation and other medical problems due to being allowed by the nursing staff to sit in a wheelchair or lay in bed for hours on end. With the Merry Walker, a resident can maintain ambulation independence, obtain exercise and social interaction as well as reduction in the unnecessary medical complications.

If you have further questions, I look forward to speaking with you. Again, thank you for developing and marketing such an important and necessary medical products.

Sincerely,

Deborah C. Karas, RN, BC, MS
President

North Carolina Department of Human Resources
Division of Mental Health, Developmental Disabilities
and Substance Abuse Services
Broughton Hospital
1000 South Sterling Street • Morganton, North Carolina 28655
Area Code 704/433-2111
Courier 06-13-21

James B. Hunt, Jr., Governor
C. Robin Britt, Sr., Secretary

M. F. Hall, Jr.
Director

July 12, 1993

Mary Harroun
Merry Walker Corporation
1357 Northmoor Court
Northbrook, IL 60062

Dear Mary:

My usual apologies for the delay in getting the results of the Merry Walker Study to you but at long last they are enclosed. As you can see, I have enclosed the approval from the Human Research and Development Committee, the Research Protocol, the results, and a discussion of the results. If one takes a quick look at the results, one might be somewhat disappointed i.e., the number of falls and the number of restraints and the number of PRN medications is not that dramatically different. However, if one looks at the ambulatory outcome, that is the number of people that came in nonambulatory and managed to progress to an ambulatory status, one sees that ten persons went from nonambulatory to ambulatory status that had the use of the Merry Walker whereas only one patient without the use of the Merry Walker became ambulatory.

I think these ambulatory statistics speak for themselves and more than justify the cost and use of the Merry Walker in terms of keeping people ambulatory and preventing the usual complications that come from loss of mobility. Please give me a call if you have any questions about these results. I will be in touch with you, and I am working with the hospital now to buy the four Merry Walkers which we used in the study. My sincere thanks to you for your help with this.

Sincerely,

Bob Ratcliffe, MD

wb

Enclosures

GRS

FOURTH EDITION 1999 – 2001

GERIATRICS REVIEW SYLLABUS

A Core Curriculum in Geriatric Medicine

BOOK 1 ■ SYLLABUS

Elizabeth L. Cobbs, MD
Edmund H. Duthie, Jr, MD
John B. Murphy, MD
EDITORS

American Geriatrics Society
New York, New York

KENDALL/HUNT PUBLISHING COMPANY
4050 Westmark Drive Dubuque, Iowa 52002

Table 24—The Roles and Sites of Intervention by the Rehabilitation Team

Discipline	Primary Focus	Tasks
Physical therapist	Impairment, functional limitation	Evaluation of joint range of motion Exercise training to increase range of motion, strength, endurance, and coordination Evaluation of mobility and need for mobility aids Treatment with physical modalities (heat, cold, ultrasound, massage, electrical stimulation)
Occupational therapist	Functional limitation, disability, handicap	Evaluation and training in self-care activities and activities of daily living Evaluation and training in cognitive activities of independent living skills (handling money, safety in the kitchen) Evaluation of home safety
Speech therapist	Impairment, disability	Evaluation and training in all aspects of communication Therapy for swallowing disorders
Nursing personnel	Disease-to-handicap continuum	Facilitation of independence with activities of daily living Education of patient and family
Social worker	Handicap	Evaluation, disposition, and liaison with the community Counseling
Dietitian	Impairment	Assessment of nutritional status and adjustment of diet to maximize nutrition
Recreational therapist	Disability, handicap	Assistance with maintaining social roles

scribing a device because medical or surgical treatment for individual diseases and impairments may be more effective or may enhance the usefulness of these devices.

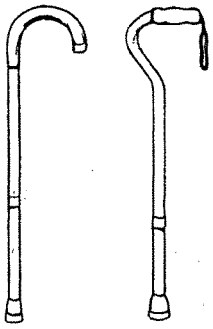
Mobility Aids

Canes typically support 15% to 20% of the body weight. The tips, handles, materials, and lengths of canes vary. As the number of tips increases, the degree of support also increases, but the cane becomes heavier and more awkward to use. The cane tip is fitted with a 5 cm diameter rubber tip with a concentric ring to prevent slipping. The handle of the cane may be curved or have a pistol grip; the pistol grip offers more support but is less aesthetically pleasing to some people. Canes can be made of a variety of materials, but most are made of wood or light-weight aluminum. The length of the cane is important for stability. Some canes are adjustable, but wooden canes must be cut to size. One of three methods may be used to evaluate the proper cane length: measuring the distance from the distal wrist crease to the ground when the patient is standing erect, measuring the distance from the greater trochanter to the ground, or measuring the distance between the ground 15 cm in front of and to the side of the tip of the shoe and the elbow flexed at 30 degrees. The first method is preferred.

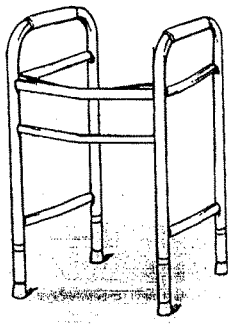
Crutches can support full body weight but are seldom used with older persons. Problems with crutches include the large amount of arm strength required, the risk of brachial plexus injury, and the necessity to use an unnatural gait pattern.

A walker is prescribed when a cane does not offer sufficient stability. A walker can completely support one lower extremity but cannot support full body weight. Walker types include pick-up and wheeled walkers (Figure 8). The pick-up walker is lifted and moved forward by the patient, who then advances before lifting the walker again; the result is a slow, staggering gait. It requires strength to repeatedly pick up the walker and cognitive ability to learn the necessary coordination. A wheeled walker allows for a smoother, coordinated, and faster gait and takes advantage of overlearned gait patterns. It is more likely to be correctly used by persons with cognitive impairment. The most commonly used type is the two-wheeled walker, which brakes automatically with increased downward pressure. Four-wheeled walkers are rarely used because they are less stable and more difficult to control, although they are occasionally useful for persons with Parkinson's disease. Three-wheeled walkers may offer some advantages in ease of turning but are not yet in common use. The Merry Walker® Ambulation Device has a seat and bars all the way around. It is the same size as a wheelchair and is best reserved for those with severe balance problems. It is also useful for severely demented patients.

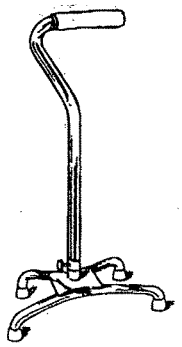
Figure 8—The single-point cane, quad cane, hemiwalker, stationary walker, and Merry Walker® Ambulation Device.



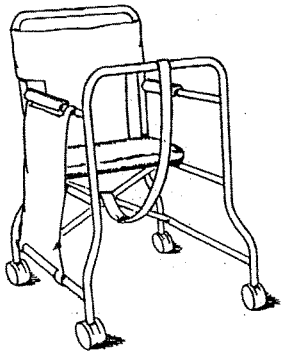
(a) Single-point canes assist with balance by providing additional sensory input and widening the base of support. Canes also can reduce lower-extremity weight bearing by transfer of weight bearing through the upper extremity. Light-weight metal canes can be adjusted for proper height. Use of a rubber tip on the cane prevents slipping.



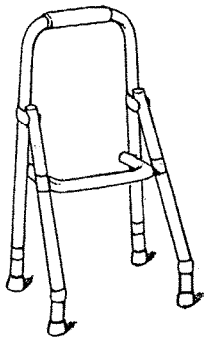
(d) The stationary, or pick-up, walker, offers four-point, wide-based support and like axillary crutches can allow for non-weight-bearing movement. The pick-up walker must be lifted and advanced with each step or two. It requires strength, coordination, and the cognitive capacity to learn its proper use. Wheeled walkers may be useful for patients who have difficulty with lifting and coordinating the use of the standard walker (eg, Parkinson's disease patients). Wheeled walkers are generally less stable, however.



(b) The quad cane provides an increased base of support for added stability. Small-based and wide-based varieties are available. Quad canes are adjustable in height, and the orientation of the rubber-tip prongs is also adjustable for use in either the right or left hand.



(e) The Merry Walker® Ambulation Device is foldable and comes in several sizes. It is lightweight and sturdy, resting on four wheel casters. It is designed to provide additional safety and support while continuing to foster independence and freedom of movement. It is well suited for persons with severe impairments in balance and cognition.



(c) The hemiwalker is useful for persons with only one functional upper extremity (eg, with upper-extremity hemiplegia following stroke). Like a walker, it provides a wide, four-point base of support with greater stability than a quad cane. Like a cane, however, it is easily used with one hand.

VA MEDICAL CENTER
Edith Nourse Rogers Veterans Memorial Hospital
200 Springs Road
Bedford, MA 01730

• February 13, 2002 In Reply Refer To: 518/182B

Mary Harroun, M.S., N.H.A.
Merry Walker Corporation
9804 Main Street
P.O. Box 9
Hebron, IL 60034

Dear Mary,

Thank you for bringing to my attention the classification of Merry Walker as a "chair that prevents rising" in the MDS manual. This classification is completely wrong and is resulting in great disservice to individuals that could benefit from using Merry Walker.

In our long experience with Merry Walker, which we use extensively for maintaining ambulation in individuals with advanced Alzheimer's disease, Merry Walker not only does not prevent rising, it actually promotes and stimulate it. Patients are stimulated to walk when they are using Merry Walker and use the seat only when they get tired. The belt is preventing them from falling to the ground but does not restrict in any way their mobility. Actually, any wheel chair is much more preventing rising than Merry Walker, especially if the foot supports are used.

We have found that the use of Merry Walker increased ambulation and engagement with the environment and decreased daytime napping. Merry Walker also improved patient's mood and prevented patient's falls.

I hope that you will be successful in getting the MDS manual amended. Caregivers should be encouraged to use Merry Walker and not discouraged by a senseless statement.

With best regards.

Yours sincerely

Ladislav Volicer, M.D., Ph.D.
Professor of Pharmacology and Psychiatry,
Boston University School of Medicine,
Clinical Director, GRECC.

DEPARTMENT OF VETERANS AFFAIRS
Edith Nourse Rogers
Memorial Veterans Hospital
200 Springs Road
Bedford MA. 01730

In Reply GRECC/182B
April 24, 1997

Mary Haroun
Merry Walker Corporation
9804 Main Street
Hebron, IL 60034

Dear Mary,

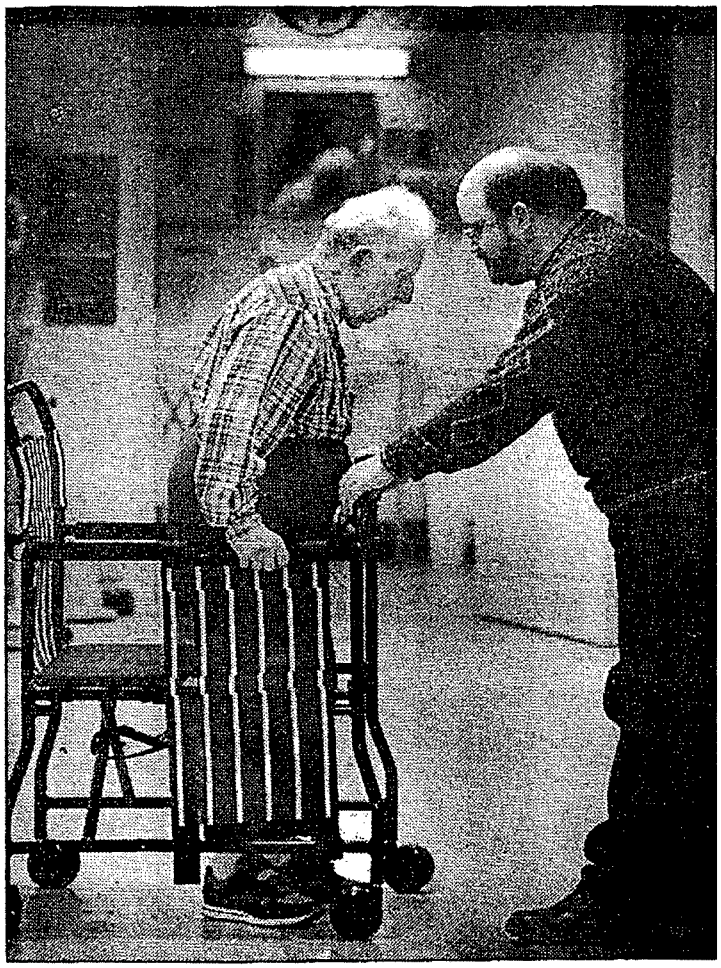
I am forwarding for your review a copy of the newspaper article, and more importantly photograph, which appeared in the Boston Herald, March 16, 1997. Although the caption is less than adequate, the photo depicts one of the eight subjects involved with the Merry Walker research project here at the Bedford VAMC.

As I review the multitude of data which we have collected, in hopes that it will soon be thoroughly analyzed, I am struck by the overwhelming sense of success this project has enjoyed. This sense has been reflected not only by my observations, but also, by the many family members and patients who experienced the walkers in action. When the walkers are taken out during visiting hours there is typically a sense of skepticism -- "That's an interesting contraption." This quickly turns to outright amazement -- "Isn't that marvelous! I've never seen Joe walk."

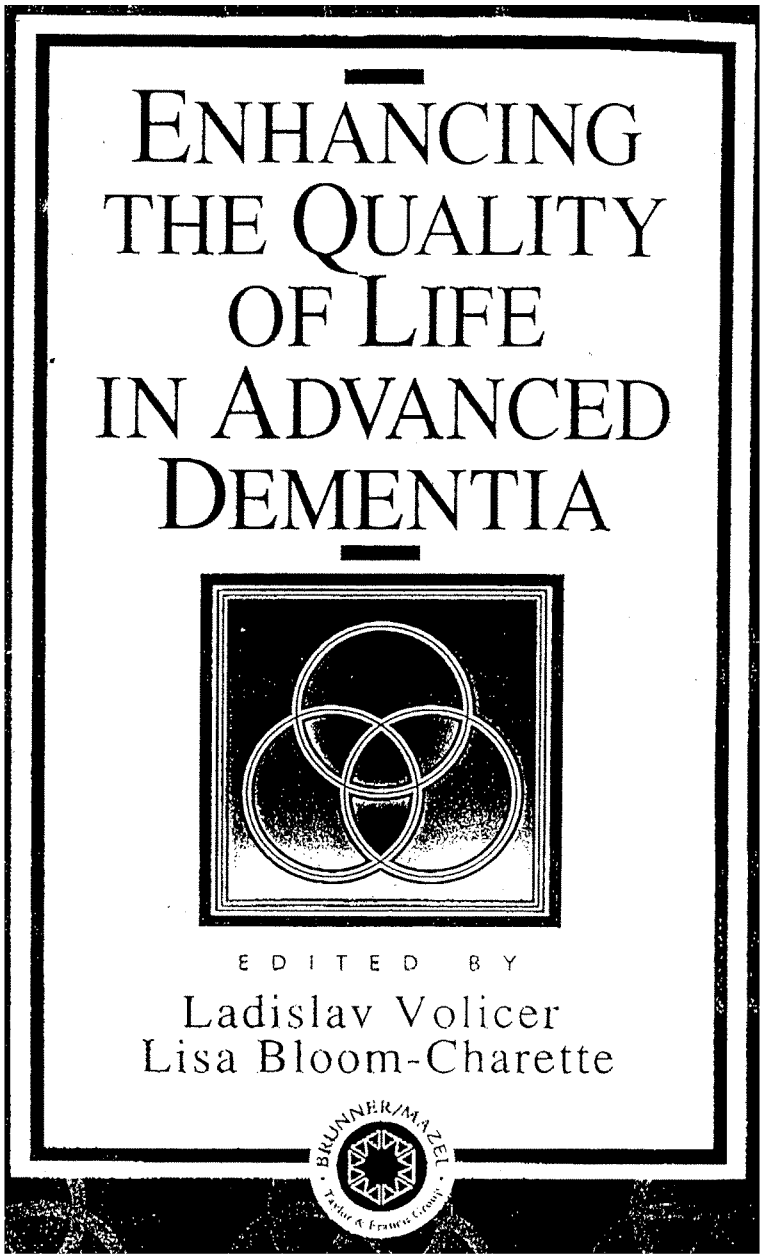
As you know as a government employee I am unable to endorse any commercial product. I must however express my appreciation to you for helping to support this research. I am confident that my patients and their families would likewise extend their thanks for the opportunity to enhance the quality of life on the Dementia Special Care Units.

Sincerely,

Scott A. Trudeau, OTR/L
Scott A. Trudeau, OTR/L



TREATMENT: A patient works with an Alzheimer chair at Veterans Administration Hospital in Bedford. Key findings are changing methods of treating and preventing Alzheimer's Disease. Staff photo by Mark Garfinkel


ENHANCING
THE QUALITY
OF LIFE
IN ADVANCED
DEMENTIA
EDITED BY
Ladislav Volicer
Lisa Bloom-Charette
BRUNNER/MAZEL
Taylor & Francis Group

5
CHAPTER

Scott A. Trudeau

Prevention of Physical Impairment in Persons with Advanced Alzheimer's Disease

One of the hallmarks of Alzheimer's disease is progressive physical decline. This decline is manifested in both decreased ability to perform activities of daily living and deterioration of neuromotor function. The degeneration of motor function may be caused by rigidity, decreased strength and endurance, impaired sensory awareness, or apraxia, singularly or in any combination. In spite of the often profound limitations of motor performance and functional ability in persons with Alzheimer's disease, little attention is paid to their need for rehabilitative care. This lack of attention frequently is written off as obvious in light of a pervasive belief that persons with advanced Alzheimer's disease do not possess any rehabilitative potential. But, are physical deformity and immobility inevitable consequences of this disease process? This chapter reviews the issues of impaired functional performance and decreased mobility and outlines some possible strategies to intervene to improve quality of life.

Background

Functional Decline and Staging in Alzheimer's Disease

Functional deterioration as a result of Alzheimer's disease is well established in the literature (Corey-Bloom et al., 1995; Geldmacher &

Whitehouse, 1996; Reisberg, Ferris, & Franssen, 1985; Volicer, Hurley, & Mahoney, 1995). Furthermore, there are those who argue that functional decline occurs predictably, in the reverse order of normal development. Many of the scales developed to track stages of Alzheimer's disease rely on this as a basic assumption (Cohen-Mansfield et al., 1996). Reisberg et al. have done much of the work in this area, seeking to define the process of deterioration in functional terms.

In their earlier work, Reisberg, Ferris, DeLeon, and Crook (1982) developed the Global Deterioration Scale. This scale was later incorporated into the more comprehensive Functional Assessment Staging Tool (FAST; Reisberg et al., 1985). For purposes of this discussion the FAST tool is highlighted; the reader needs to keep in mind that the stages identified were defined initially in the Global Deteriation Scale. In other words, the seven stages of the Global Deteriation Scale were expanded into seven stages with nine substages in the FAST, for a total of 16 possible levels. The FAST ranges from 1 (no impairment) to 7f (loss of consciousness). The following is a summary of the functional status at each of Reisberg's FAST stages:

1. No impairment
2. Difficulties finding words
3. Impaired job performance
4. Assistance required with complex tasks (finances etc.)
5. Assistance required selecting proper clothing

6a. Assistance required donning clothing
6b. Assistance required with bathing
6c. Assistance required with toileting
6d. Urinary incontinence
6e. Fecal incontinence

7a. Speech decrease to approximately a half dozen intelligible words
7b. Speech decrease to one intelligible word
7c. Inability to ambulate
7d. Inability to sit up
7e. Inability to smile
7f. Loss of consciousness

Nolen (1988) provides statistical support for Reisberg's notion that activity of daily living functions are lost in reverse order of the developmental acquisition of these skills in children. In more recent work, Cohen-Mansfield, Werner, and Reisberg (1995) explored these principles of functional decline within a general nursing-home population. This work sought to further investigate the order in which these functions are lost, and to correlate this to losses in cognition. This work correlates with previous findings that there is a definitive order in which activity of daily

living abilities are lost. Understanding the magnitude and sequence of this decline in functional ability is necessary to guide professional interventions; however, it appears to over simplify the issues one deals with clinically.

Clinically, there is a need to consider the unique circumstances of each person with Alzheimer's disease. Most individuals do not fit neatly into scales such as the FAST. In working with an individual with advanced Alzheimer's disease, it may be easier to perceive his or her status in terms of a given level, but this may give too much power to the disease process and blind the clinician to opportunities for intervention. Clinicians may reach a point at which all functional decline is attributed to the disease progression, rendering them helpless and hopeless to intervene.

A more general conceptual framework of function may be indicated in persons with advanced Alzheimer's disease. Leidy (1994) maintains that functional status is a multidimensional concept lacking a uniform definition. She proposes that functional status encompasses an individual's ability to perform the necessary activities to fulfill the demands of one's usual routine. Thus, there is a significant contextual component to functional status. Functional status is further defined in her framework by an interplay between functional performance (what one does) and functional capacity (one's maximum potential).

No matter how function is conceptualized in persons with advanced Alzheimer's disease, the losses and changes that occur are profound and warrant closer scrutiny. It is essential to understand some of the neuropathological changes that may occur as the disease progresses.

Neuromotor Deterioration

Souren, Franssen, and Reisberg (1997) look more specifically at functional loss in terms of neuromotor changes in persons with Alzheimer's disease. These authors describe *paratonia*, an involuntary rigidity response to passive movement. Paratonic rigidity, also called *gegenhalten*, is differentiated from Parkinsonian rigidity by the absence of cogwheel effect and inconsistency throughout the arc of passive movement. This rigidity may recede suddenly only to resume moments later. Paratonia continues to increase in severity throughout the progression of Alzheimer's disease and may result in generally flexed posture, labile balance, and falls. As these involuntary changes occur, it is imperative for caregivers to adapt interventions and the environment to compensate for the effects of this rigidity. Souren et al. speculate that paratonia may be a significant contributor to the development of contractures in late stages of

Alzheimer's disease, because loss of balance and frequent falls often lead to immobility.

Impairments in mobility frequently occur as a part of the aging process. Decreased visual and auditory acuity, limited endurance and strength, and changes in coordination and flexibility have all been associated with "normal" aging. In addition to the obvious neuromuscular influences that may limit mobility, issues of disuse must also be considered. Disuse can result in the debilitating effects of inactivity including a generalized state of physical deconditioning for the elder (Bottomley, 1994).

Losses of muscle mass, strength, and flexibility all have been linked to inactivity. It has been estimated that full bed rest may result in as much as a 3% decrease in strength per day (Payton & Poland, 1983). The issue of inactivity is especially poignant for the individual with advanced Alzheimer's disease. As noted previously, functional and behavioral changes that occur as part of the disease process may predispose individuals with advanced Alzheimer's disease to profoundly limited activity levels. Consequently, persons with Alzheimer's disease endure the double jeopardy of falls and immobility (Alexander et al., 1995).

Morris, Rubin, Morris, and Mandel (1987) suggest that impaired ambulation and potential for falls may increase the rate of institutionalization three-fold for persons with Alzheimer's disease as compared with cognitively intact elders. Institutionalization clearly complicates matters for the person with Alzheimer's disease. Carlson, Fleming, Smith, and Evans (1995) describe the phenomenon of *excess disability*, which is the difference between functional performance and functional capacity. Therefore, behavioral and functional problems that are disproportionate to the level of cognitive impairment may be attributable to iatrogenic effects of the institutional setting (Post & Whitehouse, 1995).

Satin (1994) labels these iatrogenic factors "health care–produced disabilities." He warns that intervention, however well intended, may be more disruptive than helpful to an elderly person. Some common iatragenic effects of healthcare for persons with Alzheimer's disease may include loss of autonomy; depression; dependence in activities of daily living; decreased self image; compromised dignity; inactivity, which can lead to muscle atrophy; and altered awareness caused by medications (Post & Whitehouse, 1995; Satin, 1994).

All of these risk factors are magnified further for individuals with advanced Alzheimer's disease in long-term care settings if physical restraints are used. Post and Whitehouse (1995) reflect this sentiment, outlining the hazards of restraint use including strangulation, immobility, and physical deconditioning. Although restraints often are employed to enhance safety, there is limited evidence supporting this rationale.

The body of literature exploring the effects of restraint-reduction programs with the elderly has grown since the Omnibus Budget Reconciliation Act (1987). These regulations were implemented in October of 1990. Part of their mandate specifically addresses that nursing-home residents have the right to be free of physical or chemical restraints, other than those required to treat "medical symptoms" (Department of Health and Human Services, 1989).

Evans and Strumpf in 1989 attempted a comprehensive review of the literature on physical restraint of the elderly and found that most citations centered around auto-safety devices, restraint use in psychiatry, and laboratory animal-immobilization techniques. These researchers estimated a prevalence of restraint ranging from 25% to 85% in nursing homes.

Tinetti, Liu, Marrotoli, and Ginter (1991) describe physical (mechanical) restraints as devices applied to impede or limit movement. These authors studied 12 nursing homes, caring for 1756 residents over the age of 60 years. Of this sample a full 66% experienced physical restraint over the course of the 1-year study. Unsteadiness or risk for falls and disruptive behaviors were cited as the most common explanations for restraint.

In a related project, Tinetti, Liu, and Ginter (1992) explored the impact of mechanical restraints on fall-related injuries. These authors report no decrease in falls or serious injury among residents receiving restraints as compared with nonrestrained residents. They speculate that changes in strength and balance as a result of immobility may have contributed to this finding.

Neufeld and Dunbar (1997) report that in the 7 years since the implementation of the Nursing Home Reform Act, the prevalence of restraint use in nursing homes has decreased from 40% to 19%. In a series of articles, these authors and colleagues describe a multistate intervention and education strategy targeted at direct-care and administrative long-term care personnel. They implemented a multidisciplinary education session (2 days), followed by quarterly on-site consultation. Their team consisted of a nurse, physician, occupational therapist, and physiatrist. The homes studied experienced a 90% decline in restraint use, from 41% to 4%. They strongly advocate the multidisciplinary nature of developing restraint alternatives, especially the use of occupational and physical therapists to assess mobility, prevent falls, and promote proper positioning (Cohen, Neufeld, Dunbar, Pflu, & Breuer, 1996; Neufeld & Dunbar, 1997; Neufeld, Libow, Foley, & White, 1995).

Similarly, in their review article, Evans and Strumpf (1989) advocate rehabilitative therapies as integral in the establishment of alternatives to restraint. Alternative environmental adaptations, such as redesigning furniture or introducing appropriate assistive devices, also are prevalent in this literature.

Addressing the multiple losses and challenging behavioral issues that

the individual with Alzheimer's disease may present can be an awesome task. In spite of the fact that Alzheimer's disease is irreversible, it is important to recognize opportunities for intervention that may impact the individual positively. One of the most obvious areas for intervention, yet often overlooked, is the environment supporting the individual with Alzheimer's disease.

Kiernat (1982) describes the environment as "the hidden modality" in light of the impact it may play in the care of older adults. Lawton (1983) acknowledges the implicit and explicit demands the environment places on an individual to function. Skolaski-Pellitteri (1983) and Corcoran and Gitlin (1991) address more specifically the role the environment can play in dementia care. Two critical areas that the environment can influence significantly are safety of the individual with Alzheimer's disease, and promotion of maximal function.

Intervention Strategies

Because the scope of the neuromotor changes in question is so broad and often variable, so must the programs be to treat them. The single most important requirement of any intervention is that it must be individualized to meet the needs of the specific person in question. Unfortunately, there is no quick-fix approach to this issue. Further, in order to ensure the best outcome, an interdisciplinary approach to treating functional and mobility losses is a requirement of any intervention. This approach must include and respect the expertise of rehabilitative staff (occupational or physical therapy), nursing, physicians, pharmacists, and so forth.

Interdisciplinary approaches can be achieved best through the collaborative inception and development of an idea. There are currently many intervention strategies being tested at a veteran's hospital in the northeastern United States, to address the functional and mobility needs of dementia special care unit residents. As further definition of the precise neuropathological losses involved in Alzheimer's disease occurs, this repertoire is subject to change and expansion.

Prior to initiation of any intervention strategy, comprehensive and complete assessment must be performed. This patient assessment is best accomplished through an interdisciplinary team process that extracts multiple perspectives on the root cause of the immobility and functional decline. Once the assessment determines that there is a need for intervention, careful discussion as to the best strategy for the individual is key.

Intervention strategies can be as simple as encouraging nursing staff to assist the individual with ambulation as much as possible throughout the day. If more specific rehabilitative needs are present, the person is likely to fit into one of the following categories:

- *Acute change in ambulatory status (less than 1 month)*: This is often the result of intercurrent infection and immobility from short-term bed rest, orthopedic injury, or an acute cerebrovascular accident. In these cases rehabilitative potential is generally relatively good.
- *Long-standing immobility*: This may be the result of prolonged bed rest or confinement in a chair. Rehabilitative potential is greatly influenced by the individual's motivation and mental status.

In considering the rehabilitative potential of an individual, it is imperative that one consider the implicit and explicit influences from the environment. The success of any intervention is correlated directly with nursing-staff investment. Thus, interdisciplinary collaboration and communication are again essential.

The following is a case example of a patient who represents the first category, acute-onset immobility:

> Mr. G is an 81-year-old, married White male who is newly admitted to a dementia special care unit from home, where he resided with his wife. Within 14 days following his admission, significant functional decline is observed and noted. He no longer ambulates, and both of his lower extremities are experiencing significant edema. He transfers from bed to chair with moderate to maximal assistance from caregivers. He is placed in a large geriatric chair in a reclined position to elevate his edematous legs. He is becoming increasingly agitated and vehemently complains of being confined in the chair. There is an increase in pharmacologic interventions to control this agitation.
>
> Discussions with the nurse practitioner and the physician reveal no significant precautions; thus, a fairly aggressive rehabilitation plan commences. This includes daily occupational therapy to increase endurance and independence with self-care activities and improve functional mobility. Inherent in this plan is the ongoing education of nursing staff as to strategies to help Mr. G maximize his independence. After 3 weeks of this intervention, Mr. G is able to assist with most of his morning care tasks including walking to the bathroom with minimal assistance and standing at the mirror to shave independently. Although he has shown significant improvement, his walking endurance is still compromised, and his sense of being confined in a chair is a source of great frustration for Mr. G.
>
> At this time it becomes clear that Mr. G is a candidate for assistive devices, but which? Here staff initiates two strategies. First, in a collaborative effort physical therapy and occupational therapy fit Mr. G to a personal wheelchair. The chair is fitted so that it is low to the ground with a slight anterior angle to the seat to facilitate Mr. G's ability to self-propel the chair with his feet. He readily accepts this device and quickly is maneuvering about the environment.
>
> Second, Mr. G is introduced to the Merry Walker (Merry Walker Corp., Richmond, IA), which allows him opportunities to stand and walk without direct assistance from staff.

The case of Mr. G clearly presents the fluidity and complexity of the assessment and intervention processes. Two of the interventions described previously are noteworthy and are described further—first, the physical and occupational therapy collaboration and intervention for fitting wheelchairs. At this VAMC setting, the physical therapy area is far removed from the dementia special care unit. For many demented patients the stress of leaving the unit, and the safety risks that may be involved, in the past prohibited them from accessing services. To rectify this, a specialized wheelchair clinic has been established on the dementia special care unit. Further, this has provided the opportunity for direct collaboration between physical and occupational therapies.

Second, the Merry Walker is a steel-constructed walker on four wheels. This walker includes a built-in seat behind the individual that enhances safety by limiting falls. This assistive device was essential in the case of Mr. G to allow him continued mobility in an upright position. The walker also compensated for his decreased endurance, allowing him to safely walk with modified independence, and he quickly learned to sit down if fatigued.

This case also reflects intervention strategies related to other areas of physical loss for Mr. G, specifically self-care deficits. It would have been easy to attribute his inability to perform activities of self-care as merely an inevitable consequence of his advanced Alzheimer's disease. However, upon careful consideration of this case, it became clear that these functional losses were more acute in nature, and thus rehabilitative potential was apparent.

Occupational therapy interventions focused on familiar activities of daily living, as a means to both increase physical mobility and endurance and restore functional independence. This patient was able to reclaim abilities to assist with dressing and grooming tasks, much to the surprise of direct-care staff.

☐ Walking and Quality of Life

The need for persons with Alzheimer's disease to retain some sense of purposeful activity may be evidenced in the frequently described persistent wandering of some patients. Whether anxiety-driven or not, the need to move seems to be retained late into the disease. The deeply ingrained nature of walking is consistent with the FAST scoring of loss of ambulation ability into the last quarter (12th out of 16 items) of the scale (Reisberg et al., 1985). Lawton, Devoe, and Parmelee (1995), Teri and Logsdon (1991), and Alberi et al. (1996) laid the groundwork for consideration of the consequences of seemingly insignificant daily activities on quality of life. In

fact, within the context of the profound losses experienced in Alzheimer's disease, it may be a misnomer to label *any* activity "insignificant."

One study in a general nursing-home population attempted to measure the effect of a walking program on general physical condition and quality of life. These researchers provided 12 weeks of an individualized walking program at a resident-selected pace. They found that the frail elderly involved were able to adhere to the rigors of the program and significantly increase their walking endurance capacity, without any adverse effects (e.g., falls or cardiovascular incidents) being reported. Although these results do not directly reflect quality of life, they support the notion that even chronically ill, frail elders can tolerate and benefit from increased ambulation (MacRae et al., 1996)

Friedman and Tappen introduced Alzheimer's disease patients to a "planned walking" intervention in 1991. This pilot study investigated the effect that walking had on the communication skills of demented individuals. Thirty subjects (15 in each group) participated in this study at two long-term care sites. Half the subjects received the walking intervention with conversation for 30 minutes three times per week for 10 weeks. The second group received a conversation-only intervention for the same amount of time for 10 weeks. The results supported the hypothesis that walking could improve communication performance for persons with Alzheimer's disease.

In a recent study (Trudeau, Volicer, & Biddle, 1998) the impact that enhancing ambulation status has on quality of life of persons with advanced Alzheimer's disease was explored. This study intervened using the Merry Walker with persons with Alzheimer's disease who required assistance walking. Although the sample size was small ($n = 6$), the findings were quite promising.

The study used a cross-over design with 2-week intervals, such that subjects served as their own controls. The results of the data analysis included significant improvement of observed mood and environmental engagement, increased walking, increased interaction with others, decreased daytime sleeping, and decreased agitation as a result of using the walker during the observation period (Trudeau et al., 1998).

Conclusion

The inherent need for persons with Alzheimer's disease to continue to move is a powerful force. In conjunction with this, it is apparent that the meaning associated with walking and mobility is deep rooted. There are many academic scholars who may argue that individuals in the moderate to late stages of Alzheimer's disease could not possibly learn to use or

benefit from assistive devices such as custom wheelchairs or Merry Walkers. Further, there is often a presumption made that persons with Alzheimer's disease do not possess any rehabilitative potential, and thus rehabilitative services often are inadequately available. There is strong research and clinical anecdotal evidence to contradict these beliefs. Not only can persons with advanced Alzheimer's disease benefit from such interventions, their quality of life depends on them.

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ENHANCING THE QUALITY OF LIFE IN ADVANCED DEMENTIA

Quality of life issues, important for all, are particularly important for those who have the least control over their environment—individuals with advanced dementia. Often times, these individuals are unable to verbalize their frustrations and may exhibit agitation and other problem behaviors. Where traditional approaches may fail, this book provides new and proven techniques to enhance the lives of those individuals afflicted with advanced dementia. Instead of focusing on decreasing the problem behaviors, *Enhancing the Quality of Life in Advanced Dementia* focuses on alternative methods of increasing the positive behaviors.

The book is divided into two parts. First, generalized approaches such as Habilitation, Lifestyle Approach, Sheltered Workshop, and Functional Therapies are described. The remaining chapters focus on various activities specifically designed for this population such as Bright Eyes, Validation Therapy, Stimulated Presence Therapy, Music Therapy, SNOEZELEN®, Light Therapy, and Environmental Approaches. In addition, the book offers guidelines for the appropriateness of each technique for individuals with different manifestations of advanced dementia.

Written with a multidisciplinary team of experts in the fields of psychiatry, psychology, public health, social work, nursing, music therapy, and speech pathology, this book provides both cutting edge and cost-effective techniques to deal with this challenging population.

ABOUT THE EDITORS

Ladislav Volicer, M.D., Ph.D., is the Clinical Director of the Geriatric Research, Education, and Clinical Center (GRECC) at the Edith Nourse Rogers Memorial Veterans Hospital, and Professor of Pharmacology and Psychiatry at the Boston University School of Medicine. Dr. Volicer investigates various aspects of dementia care, including behavioral symptoms, medical complications, and eating difficulties. He has published over 200 articles and chapters, and edited two books on the clinical management of dementia.

Lisa Bloom-Charette, Ph.D., is a staff geropsychologist at the Edith Nourse Rogers Memorial Veterans Hospital in Bedford, Massachusetts. She is also a Lecturer at the Boston University School of Medicine. Dr. Bloom-Charette has consulted at numerous public and private nursing homes for the last ten years. Her clinical and research interests include behavioral management, geropsychological assessment, caregiver support groups, and aging and spirituality.

For more information, please contact:
325 Chestnut Street
Philadelphia, PA 19106
www.taylorandfrancis.com

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benefit from assistive devices such as custom wheelchairs or Merry Walkers. Further, there is often a presumption made that persons with Alzheimer's disease do not possess any rehabilitative potential, and thus rehabilitative services often are inadequately available. There is strong research and clinical anecdotal evidence to contradict these beliefs. Not only can persons with advanced Alzheimer's disease benefit from such interventions, their quality of life depends on them.

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TESTIMONY OF EDWARD L. PROBST, M.D.
PRACTICING DERMATOLOGIC PHYSICIAN
FROM COLUMBUS, INDIANA

TO THE
COMMITTEE ON SMALL BUSINESS

HEARING ON
CLINICAL LABORATORY IMPROVEMENT ACT OF 1988

OCTOBER 3, 2002

WASHINGTON, D.C.

Mr. Chairman and members of the Committee on Small Business,

Thank you for the opportunity to share with the Committee concern about the effects of CLIA on small medical practices.

Is CLIA necessary for the small office setting? Are their requirements helpful to the patients in the small office setting? Is the additional cost and time justified?

Have our patients been better served since CLIA?

CLIA has increased the cost and increased the time required for filling out the application and the certificate for the inspection. It also causes burdensome and unnecessary recordings, unnecessary meetings and added cost of formally typing and reporting on the unnecessary meetings.

Care of patients is compromised by having to have one eye on satisfying the bureaucratic requirements instead of having both eyes fully on the patients. This is not in the patients best interest.

There is loss of time with patients. All of these CLIA requirements detract from the time available. Since there is only so much time, this has to come from patient care and this actually decreases the quality of patient's care.

They have also decreased physician and staff time for patient care and interaction.

There is definitely less physician, nurse staff and patient satisfaction because of the burdens of these requirements.

CLIA has adversely affected our practice.

The goal of our medical practice is to provide the best, most efficient and cost effective care to the citizens in our area.

We perform few laboratory services, but the ones we perform are best performed by a physician and at the time of service, so the patient can be diagnosed and treatment started immediately.

We are required to be CLIA approved to perform any test. The tests we perform during the patient visit are scrapings for fungal diseases, scabies, lice, etc.
It is essential to the well-being of our patients and community that these diagnoses be made immediately. Please consider the consequences of delayed diagnosis and treatment of contagious scalp fungus, scabies and lice to a school, nursing home population, or even in your own family.

Correct diagnosis and prompt treatment is our goal and in the best interest of our patients and of our community.

Cost is increased when these tests are performed at a hospital laboratory.

We have always maintained a system so that all laboratory tests sent out are correctly recorded on the patient's record. The systems used by major laboratories do not work best in the small office. The CLIA, one system fits all, should not be forced on the small office.

Before CLIA, we read our scrapings, and simply recorded the results in the patients record and explained them to the patient. CLIA requires unnecessary requisitions and logging which are time consuming and add no value.

What might be appropriate for a large laboratory using technicians instead of physicians for doing the service is not appropriate for a small office where the test is done by the physician.

Because of the increased requirements and burden of CLIA, we no longer do Mycocel fungal cultures or viral scrapings (Tzanck smears) to diagnose herpes simplex or herpes zoster. This is unfortunate for the patients.

We offer our services in three smaller communities one day a week. Because of the staff required, time and cost to comply with CLIA regulations, we are unable to offer laboratory services in these locations. The scrapings are packed and transported back to the main office for reading.

This is very inefficient and risks the specimens drying out, being lost or damaged. The CLIA regulations cause delayed diagnoses and poorer service than was previously provided in these satellite offices.

Numerous forms and reports must be generated to satisfy the CLIA inspector (see attachments). The annual activity calendar for CLIA shows that there are 46 required meetings, activities or reports in addition to the following:

1) A written requisition is required for each test. (Unnecessary because the result is written in the record by the physician during the patient visit)

2) A laboratory requisition and report log must be completed for each test that is done. (Unnecessary because the result is written in the record by the physician during the patient visit).

3) The laboratory refrigerator temperature chart: The temperature be taken, recorded and initialed on each working day, then reviewed monthly by the QA person.

4) The room temperature chart: The temperature must be taken, recorded each working day and initialed, then reviewed monthly by the QA person.

5) The freezer temperature chart: The temperature must be taken, recorded each working day and initialed and reviewed monthly by the QA person.

6) The autoclave run sheet: Must be recorded each time the autoclave is used and initialed then reviewed monthly by the QA person.

7) The autoclave maintenance record.

8) Fire extinguisher inspection record.

9) Cleaning schedule for each exam room and nurse station.

Nothing is achieved by these requirements that was not done prior to CLIA.

CLIA has a number of Quality Assurance requirements that do not seem appropriate for the office in which the physician does all of the testing. In order to satisfy some of these requirements, the Indiana University Department of Dermatology will project a slide, with or without scabies. When projected on the screen, we fill out the answer sheet indicating whether or not scabies is present; likewise, for fungal scrapings, for hyphae and spores, etc. For histopathology reading, ten slides are presented and the physician will record the diagnosis.

In our office, we also have each physician review a slide to fulfill the CLIA Quality Assurance requirement. This meets the CLIA requirement but actually is not helpful to maintain or improve one's diagnostic skills.
We have always shared difficult slides with the other physicians in our office to sharpen our skills. We also take meaningful courses to keep current and sharpen our skills as well as reading journals and appropriate medical text. These are some of the ways professionals keep current, review and provide accurate diagnoses on clinical material.

CLIA Quality Assurance is neither realistic not helpful to the physician. It is another frustrating, time consuming exercise that might be helpful for technicians but not for physicians.

The increased time and cost taken in the unnecessary rules, regulations and ineffective quality assurance measures only decrease of time available for meaningful quality assurance programs that a professional will seek to have if he is providing these services. I feel that this burdensome, time consuming and costly regulation along with the many others that we are under interferes with our ability to have the time and recourses for meaningful continued education.

CLIA has unreasonable rules that create "errors". The program then is judged by the number of "errors" that have been corrected. In my opinion and in our experience, "errors" (infractions) are primarily related to paperwork which the program has created and which do not affect the quality of service. On one occasion, our inspector said we must have "errors" or he will assume we are fudging the data.

The Clinical Laboratory Improvement Act of 1988 was written in response to large commercial laboratories' failure to accurately interpret mail-in pap smears, however, the act extended into every medical office that offered laboratory services.

The application of large laboratory rules to the small office has created hardship, increased cost, burdensome requirements and much wasted time in small offices.

Many physician offices stopped offering laboratory services causing patients to have less accurate diagnoses or the increased inconvenience and expense of testing at other laboratories. As well as, delayed diagnosis and treatment.

To better serve our patients, physicians need relief from the unnecessary burdens of CLIA. Waiving all microscopic studies in the small office, eliminating unbeneficial paperwork (documentation), allowing the professional to determine the best Quality Assurance and continuing education would be a start.

Thank you Mr. Chairman and members of the Committee on Small Business. I will be happy to respond to any questions at your request.

Sincerely,

Edward L. Probst, MD

STATEMENT OF

W. PATRICK DAVEY, M.D.

ON BEHALF OF

THE AMERICAN ACADMEY OF DERMATOLOGY ASSOCIATION

BEFORE THE

HOUSE SMALL BUSINESS COMMITTEE

ON

CLIA AND CMS REGULATION OF SMALL BUSINESSES

WASHINGTON, D.C.

OCTOBER 3, 2002

Introduction

Chairman Manzullo, Chairman Pence, and Representative Velazquez, I appreciate the opportunity to appear before you today to present this statement on the Clinical Laboratory Improvement Act Amendments of 1988, known as CLIA, on behalf of the American Academy of Dermatology Association's 14,000 members. The AADA is the national medical society for physicians specializing in diseases of the skin, hair, and nails.

My name is Dr. W. Patrick Davey. I am a practicing dermatologist in Lexington, Kentucky and Chair of the AADA Quality of Care Task Force. I am also the managing partner of a nine-dermatologist practice and an assistant clinical professor of dermatology at the University of Kentucky Chandler Medical Center, as well as a surveyor with the Accreditation Association for Ambulatory Health Care or AAAHC. I have a longstanding interest in quality improvement in the ambulatory care setting, which I have pursued through the AAAHC and various opportunities within the AADA.

Pursuant to Rule XI clause 2(g)(4) of the U.S. House of Representatives, I declare that I have never received funds through federal grants, contracts, subgrants, or subcontracts.

Most dermatologists practice in a solo or small group setting. While my professional experience is that of a physician working in a large practice, I am also very familiar with the needs and challenges facing solo and small practices. As an AAAHC surveyor I examine and evaluate how solo and small practices are attaining overall quality standards. My work, therefore, is closely linked to compliance with quality standards, including those imposed by CLIA.

The Clinical Laboratory Improvements Act Amendments

The Clinical Laboratory Improvement Act Amendments sprang to life in 1988 in response to reports of problems with Pap smear testing that is performed almost exclusively in large independent laboratories. The goal of CLIA is to improve the quality of testing in virtually all laboratory settings where tests on human specimens are performed. Because CLIA treats big laboratories and physician office laboratories in the same manner, the AADA has expressed opposition and concerns about the 1988 CLIA law since its inception.

AADA Position Statement on the Repeal of CLIA

The AADA adopted a policy in 1993, shortly after CLIA implementing regulations took effect, opposing the 1988 CLIA law. It has not been possible to repeal CLIA or enact an exemption for physician office labs, despite the strong support of AADA and several other national medical societies for such a remedy. The AADA was a leading advocate for passage of a physician office laboratory exemption in legislation introduced in successive congressional sessions by former Representative Bill Archer (R-TX) and Senator Kay Bailey Hutchison (R-TX). The failure of the Archer-Hutchison legislation to win passage has put a damper on further legislative efforts that would exempt or otherwise extend CLIA relief to physician office labs. AADA policy, therefore, also provides that if CLIA cannot be repealed, then appropriate modifications of dermatologic laboratory procedures regulated by CLIA should be sought.

Reducing the regulatory burden of CLIA upon physicians and their patients, as the committee is seeking to do, is consistent with AADA policy. With this perspective in mind, we are pleased to offer a number of recommendations for lessening the burden of CLIA.

Compliance is Arduous for Solo and Small Dermatologic Practices

CLIA is burdensome for small and solo practices, which have limited resources with which to fulfill the array of CLIA requirements. CLIA requirements for quality assurance, quality control, patient test management, proficiency testing, and personnel – which comprise the five distinct arms of the regulation – are confusing to physicians and their staff. Not one but three federal agencies have jurisdiction over portions of the CLIA program, complicating the task of obtaining answers to questions regarding CLIA matters. About a decade ago, the AADA developed a CLIA manual for its members to simplify compliance with this important regulation. It is a testament to the complexity of this regulation that our effort to simplify compliance resulted in a binder that is several inches thick!

By 1995, shortly after CLIA took effect, approximately three out of four dermatologists eliminated or reduced in-office laboratory testing, according to an AADA survey conducted at that time. Anecdotal evidence suggests that this trend has not improved seven years later. Today, many dermatologists collect specimens and send them to an outside laboratory for testing, or send their patients to an outside laboratory for both specimen collection and testing, because fulfilling CLIA requirements is too costly and impractical. However, when patients are referred to another site for laboratory tests, it is an inconvenience and it delays results, treatment, and diagnosis for the patient and his or her dermatologists alike. This is not the preference of most dermatologists, who are residency-trained to perform a wide array of laboratory tests.

Our chief concern with CLIA, therefore, is the extent to which the regulation impedes the ability of dermatologists to provide in-office laboratory services to their patients. It is appropriate for this committee to examine the impact of CLIA on physicians and patients. Your efforts to reduce the regulatory burden posed by CLIA are a welcome development.

Reclassify Commonly Performed Dermatologic Tests

Some frequently performed dermatologic tests, such as fungal cultures, are presently classified as moderately complex laboratory tests. The AADA disagrees with this designation, and for this reason believes that the following tests should be confined to the waived and physician-performed microscopy procedures, or PPMP, categories only:

- Microscopic examination of hair morphology
- Potassium hydroxide preparation (KOH)
- Molluscum smear
- Fungal cultures
- Scabies preparation
- Tzanck smear
- Gram stain; and
- Darkfield examination.

The abovementioned tests are simple, technically easy to perform, extremely accurate and have an insignificant risk of an erroneous result. They are an integral part of the initial evaluation of a dermatologic patient. The evidence shows that putting these simple tests in higher complexity categories led to many dermatologists reluctantly choosing to reduce or eliminate in-office laboratory services, a situation that inconveniences patients, adds to the cost of medical care, and delays the diagnosis.

We are thoroughly convinced that the above-cited tests fall within the criteria for waived or PPMP tests, as specified in the CLIA statute. Accordingly, we are reiterating here our longstanding request that the eight tests mentioned above be reclassified as waived or PPM tests only. More solo and small dermatology practices might furnish in-office laboratory services if the abovementioned tests were put in the lower-complexity, waived and PPMP categories.

The Secretary of Health and Human Services Regulatory Reform Initiative

Earlier this year, the Secretary's Advisory Committee on Regulatory Reform approved 13 recommendations for improving CLIA. The AADA strongly supports the immediate implementation of these recommendations, which are listed below:

- Simplify and clarify the CLIA requirements using plain language when possible to assist laboratory and physician office laboratory (POL) staff in understanding and complying with guidelines.
- Provide information to POLs about training opportunities by the state survey agencies and other accrediting bodies such as the College of American Pathologists (CAP) and the Commission on Office and Laboratory Accreditation (COLA) to assist with interpretation and implementation of new CLIA requirements.
- Update the CLIA website and develop a more user-friendly website with links to the Centers for Disease Control's National Laboratory Training Network.
- In the application package include the CLIA requirements and a basic laboratory practices document in plain language tailored to the POL's test system menu for moderate complexity tests.
- Help laboratories interpret the CLIA requirements.
- If compliance surveys are performed by CMS on waived laboratories, the evaluations should be according to CLIA guidelines and using criteria established in consultation with accrediting agencies and physician organizations.
- Modify the Alternate Quality Assessment Survey (AQAS) self survey form as an educational tool to facilitate the survey and certification process.
- Increase the number of POL representatives serving on the Clinical Laboratory Advisory Committee (CLIAC) to more accurately reflect the number of POLs being regulated.
- Offer training and simplified guidelines to assist laboratories with the new CLIA requirements at meetings of laboratory professionals, accreditation bodies and medical organizations.
- Collaborate with the CDC on an educational brochure for POLs containing plain language interpretation of the regulatory requirements.
- Provide open forums with professional, medical, and accreditation laboratory organizations to solicit feedback on ways to improve outreach to POLs and to increase understanding of the CLIA program among physicians.
- Solicit interest in developing an educational "Clearinghouse" on the CLIA website that includes a multimedia educational program package. Interested parties would include CMS, other federal agencies, professional, medical and accreditation laboratory organizations, and CLIAC. Methods for evaluation of effectiveness of educational programs should be designed.
- Collaborate with states and private laboratory organizations to develop and promote self-assessment tools for laboratories, as well as other types of educational programs. These should include evaluation of effectiveness.

We strongly urge the Committee to use its influence to press for the immediate implementation of these improvements in how the CLIA program operates and

interacts with physicians. None of these reforms requires authorizing legislation, a fact that should help greatly with bringing about these sound improvements. These recommendations also respond directly to dermatologists' leading complaints with CLIA; namely, the lack of clarity in materials explaining proficiency testing, the need for simplification in the definitions of tests and program requirements, and assistance with preparing for inspections or applying for a CLIA certificate.

Establish Consistency in Laboratory Inspections

There is a great variance in how laboratory inspections are conducted from state to state. This lack of consistency means that the principles and goals of CLIA are being applied unevenly, creating more confusion and risk of penalization for some dermatologists and physicians than others. Therefore, the AADA encourages the appropriate federal agencies to work closely with state survey entities to ensure consistency across-the-board in how inspections are conducted in physician office laboratories. Predictable and accountable inspection processes will ensure fairness and informed compliance.

Conclusion

It is my hope that my comments offer useful guidance to you and the committee. Reclassifying the eight most commonly performed dermatologic laboratory tests as waived or PPMP tests only, working with the Secretary of Health and Human Services to achieve implementation of the Advisory Committee on Regulatory Reform's CLIA recommendations, and working with state laboratory inspectors to ensure consistency in inspections from state-to-state would make the statute less overwhelming and onerous, and perhaps more tolerable for practicing dermatologists.

It is clear that the recommendations in this statement would advance the goals of CLIA while making the regulation itself more comprehensible to physicians. And patients would be the ultimate winners if more physicians are able to furnish in-office laboratory services because CLIA is made less burdensome. For these reasons, the AADA urges the Committee to support our recommendations and work with the HHS Secretary to make these necessary changes in the CLIA program.

Thank you for considering my views on this issue of such vital importance to dermatologists and their patients. I would be pleased to answer questions from the Committee.

GREENBERG
ATTORNEYS AT LAW
TRAURIG

October 3, 2002

The Honorable Donald A. Manzullo
Small Business Committee
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Manzullo:

On behalf of the National Association for the Support of Long Term Care (NASL), we represent five major providers of portable x-ray services in the United States. They include Symphony Health Care (20 states); US Labs (9 states); HealthTrac (6 states); Portable X-ray of Nevada (5 states); and Schryver Medical (1 state). We appreciate the opportunity to discuss the Centers for Medicare & Medicaid Services' (CMS) payment for transportation fees associated with portable x-ray services. During the past several months, our interaction with CMS and the National Association for Portable X-Ray Providers (NAPXP) has proven to be very beneficial with great progress to ensure that seniors within skilled nursing facilities have access to diagnostic procedures without having to be transported to a hospital.

The issue of the transportation fee is very complex because it involves two discreet functions. First, there is a transportation fee. That fee includes the cost of traveling to the facility and the time that is spent by the x-ray technician. This part of the fee is handled through "carrier discretion." That is, the carrier has the authority to review the x-ray technician and administrative labor costs and other factors that go into that fee. The second part of the fee is the "set up fee." That part is the technician's time to set up the x-ray equipment. It is determined as part of the physician fee schedule and is modified through the physician directed CPT coding committee. I would like to explain what has occurred in improving the rates for both of these functions.

Transportation Fee

With NAPXP, we met with officials at CMS to determine the best direction to ensure carriers understood what their role was and how carriers should proceed immediately to evaluate the appropriate payment. Two steps were required. First, the regional offices needed to be informed of the carriers' authority. Second, carriers needed to be educated on the data and information necessary to proceed. Selected carriers have been notified. In addition, a Program Memorandum to the regional offices and carriers has been drafted. We are very enthusiastic with the speed and deliberate action of CMS to complete this task. We have attached a copy with modest edits that we provided to CMS officials.

GREENBERG TRAURIG, LLP
800 CONNECTICUT AVENUE, N.W. SUITE 500 WASHINGTON, D.C. 20006
202-331-3100 FAX 202-331-3101 www.gtlaw.com
MIAMI NEW YORK WASHINGTON, D.C. ATLANTA PHILADELPHIA TYSONS CORNER CHICAGO BOSTON PHOENIX WILMINGTON LOS ANGELES DENVER
FORT LAUDERDALE BOCA RATON WEST PALM BEACH ORLANDO TALLAHASSEE

Set Up Fee

To modify this effort, more complex activity must be undertaken. First, data supporting the costs of an x-ray technician was required to be submitted. It is our understanding that NAPXP has submitted that data to CMS' outside consultant. In that review, the outside consultant will evaluate the scope of the data to ensure it is adequate. They will determine whether the survey data is representative of the practice expense for the set up and meets the recently reduced statistical standards for data submission. If the survey meets those standards, the data will replace the practice expense components used by CMS in setting the rate. The second step requires representatives of a physician group with NASL or NAXPX to appear before the CPT coding committee to ask for changes to the work units used for each category of direct and indirect clinical labor, which represent the majority of the costs associated with the set up code. By the time this process began, the September agenda was closed. NASL has tentatively asked to appear in January and we need to begin identifying a supportive physician specialty group to present our case. As this Committee knows, the CPT coding committee is not controlled by CMS. It is an outside organization of the American Medical Association and they have been very helpful in educating NASL on the type of data, process and whom we need to present our case that these rates need to be increased.

There are additional complicating factors. The "set-up" procedure does not include any direct physician labor and is classified as a "zero work pool" code and it is therefore aggregated with other like-type codes. Therefore, it is difficult to get increases as the overall physician fee schedule must be updated in a budget neutral way. We have an additional burden that this code is bundled with many others. Therefore, all "zero work pool" codes get increased as a group, thereby costing more money if done individually. We have been exploring, with CMS' cooperation, if removal of the code from the "zero work pool" will result in an increased rate under the statutory directed formulas.

While we recognize that this process is more cumbersome and will take more time, we feel that CMS, CMS's consultants and the CPT coding committee have been responsive to our concerns and acted in a deliberate and straightforward fashion. We have had several phone calls, several meetings, and several e-mails and believe we are moving forward to resolve this complex billing issue.

We appreciate your oversight in this matter and appreciate the industry workgroup that has assembled to represent the needs of the portable x-ray community.

Sincerely yours,

Nancy E. Taylor

Nancy E. Taylor

for Peter Clendenin

Attachment

Program Memo

SUBJECT: Carrier review of payment amounts for portable x-ray transportation services (HCPCS code R0070)--REQUEST

Transportation for portable x-ray services (HCPCS code R0070) is paid under the Medicare physician fee schedule. There are no national relative values for this service. CMS has not established national relative values for this service because there are no national data for these services and because there are significant differences in the delivery of this service in different geographic areas. Instead, each carrier is required to determine the payment amounts for its geographic areas.

CMS has not established specific criteria that carriers should use in determining the payment amounts they establish for such "carrier priced" services. CMS has not established a specific annual update factor to be applied to these services. Mid-year adjustments are possible if the carrier believes such adjustments are appropriate. This provides carriers with the flexibility to take into account local factors affecting the level of resources required to perform this service.

Representatives of the portable x-ray industry have raised concerns to CMS and the Small Business Administration that in some states, carriers have not performed periodic reviews of their locally determined payment amounts. CMS agrees that it is appropriate for carriers to periodically review their locally determined payment amounts to determine whether the payment amounts reflect the relative resources (i.e., staff, equipment, supplies and general expenses) required to perform these services. Such periodic reviews for carrier priced services would be consistent with ~~the~~ statutory requirements. ~~that CMS review the relative values for the physician fee schedule no less than every 5 years.~~ Therefore, if asked by representatives of the portable x-ray transportation industry, carriers should work with the local industry representatives to review the payment amounts for R0070, taking into account local factors and any data available regarding the resources required to provide these services.