HEMODIALYSIS, INC.
John R De Palma, MD, CEO
1560 East Chevy Chase Drive
Glendale, CA ● 91204-4175

Voice: (818) 956-5357
Facsimile: (818) 507-5678

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June Gibbs Brown, JD, MBA
Inspector General
Department of Health & Human Services
330 Independence Avenue SW
Washington, DC 20201-0001
Voice: 202.619.3148
Fax: 202.619.0521

FedEx

RE: Office of Inspector General reports, "External Quality Review of Dialysis Facilities Two Promising Approaches"; OEI-01-00051 and "External Quality Review of Dialysis Facilities A Call For Greater Accountability"; OEI-01-00050.

Dear Honorable Inspector General Gibbs:

The above two (2) OIG Reports (OIG Reports) were sent to me – by my request – by Health Care Financing Administration (HCFA) personnel. They deal with End Stage Renal Disease (ESRD) patients and propose to improve oversight and accountability by increasing "External Quality Review…"

Major ESRD Problems Not Identified

These OIG Reports – by my careful analysis – do not address the major problems or issues of ESRD care. Indeed they propose to attempt to fix less major problems and issues by using unsupervised and untrained personnel who do not understand ESRD. The OIG Reports major premises can – I believe – be shown by *any* careful, scientific analysis to be false. Thus, any conclusions based on those false premises will most likely also be false. Though it is true that good results and data can flow from bad premises, that series of events, that probability, is on the order of less than one percent (1%). One must first identify the most significant problems and issues before proposing any solutions to those problems.

If I am correct, no improvement in American ESRD patient survival or care will be accomplished by carrying out the premises of these OIG Reports; no improvement in ESRD care even if all the goals of the OIG Reports are fulfilled exactly and expertly.

HCFA Personnel Bias Not Removed

The above OIG Reports reference reports and published documents (mostly) from the ESRD Network system (Networks). These documents were generated by the Networks as part of justifying their existance. They are thus biased in the scientific and statistical meaning of the word "biased." These documents justify the expense of the nine (or more) million dollars ($9,000,000) per year for support of the Networks by the federal government.

From the content of the two (2) OIG Reports, it would appear that your staff relied on conversations with HCFA staff as to what are the principal ESRD problems. Almost no employee of any organization is a whistle-blower. HCFA employees depend on the good-will and review process to achieve salary increases and increase in job satisfaction.

Thus the HCFA employees and consultants will – as a natural and human defence against harm – tell the OIG that they are doing a great job. To assume that what they say and what they produce is an accurate reflection of a complex medical process such as ESRD care, is probably incorrect.

All discussions, business or medical statistics, of how to properly gather then assess data indicate that personal and personnel biases must be expunged; usually by some external method of validation of said data. The OIG Reports provide no such external validation.

Patient Survival Is The Gold Standard

The gold standard of ESRD care is patient survival. Patient survival data or its inverse number, patient mortality, was *not* the main topic of the above OIG Reports. All suggestions were related to *less* important issues of ESRD care.

The ESRD program deals with patients with chronic disease. The ESRD patient have a complex set of problems which can not be likened or compared to correcting nursing home deficiencies by state inspections using state inspectors. Unlike most nursing home data, one can use patient mortality as a marker of excellence of ESRD care.

Not to first define and second to understand the principal problems of ESRD first are fatal logic and judgement errors for any investigation. I believe that the OIG Reports contain these logic and judgement errors. In the OIG Reports, there are only a few references to "patient mortality" or "mortality." There is one (1) statement that "mortality" is important… then mortality as an issue in ESRD care is dropped.

Why is Patient Mortality Lightly Dismissed?

If patient survival is the gold standard why do the OIG Reports dismiss it? Patient mortality is both the gold standard and the benchmark, upon which one should base analysis of ESRD medical and nursing care. HCFA, like most government agencies, operates under financial constraints leading to the need to provide: "The greatest good for the greatest number at the least possible cost." I have no quarrel with that premise. But, I have great quarrel with not dealing with patient survival as a first priority.

Why no Facility Specific Mortality Data?

For several years, HCFA has had the ability to provide each and every dialysis facility with facility specific data as annual gross mortality rate (GMR). HCFA should make that data available as a public document so that everyone will know where they stand as far as this measure of care. In southern California, the dialysis facility annual mortality data (which is different from the official data generated by the United States Renal Disease System (USRDS)) is available to individual dialysis facilities – once a year – as a secret document. If these mortality data were made

public, the southern California dialysis facilities with repetitive, annual patient mortality of fifty to one-hundred percent (50 to 100%) might have to do something about those horrific results.

I was on the Board of Directors and/or the Medical Review Board of Network #18 from 1990 to 1999. I requested that the dialysis facilities with the ten (10) best and the ten (10) worst dialysis unit mortalities be analyzed. Analyzed to see if there was a common thread that distinguished these two disparate groups. After analysis, we would then teach those dialysis facilities how to do better patient care. The study protocol was passed, but a final report was written out of thin air without any data collection, survey, analysis, or follow-up. Thus, that Network acted to maintain the status quo. A facility patient mortality or patient survival report is far more meaningful, simple to generate, and pertinent that the complex "individual facility reports…" which are championed in the OIG Reports.

Charts, Graphs, and other Facility Specific Reports

Most nephrologists presented with charts, graphs and statistical data may – if they are brave or naïve – respond with, "How does this incomprehensible stuff help me improve patient care?" RNs and administrators dismiss these data as being "Too complicated, I don't understand it, tell me how to help patients." Thus, I find it amazing that your staff has suggested that such "individual facility reports…" are useful tools to improve quality of care.

I wager that the staff members who advocated these type of reports in the OIG Reports do not understand these "individual facility reports…" And, also could not explain how such devices are known to improve patient survival or quality of care.

I am unaware of any hard statistical, scientific data that these colorful and complicated charts, with descriptive and inferential statistics have ever improved ESRD care used as a *prospective* tool. These are *retrospective* tools. These instruments are used to review data and often – unintentionally – cause obfuscation in the health-care worker.

If this analysis is doubted, we can conduct an inexpensive study of what someone remembers when they view or are told descriptive or inferential statistical data as charts, graphs, or tables of mind-numbing data. As a part of this study we should test all of HCFA personnel and consultants who are charged with understanding and analyzing biostatistics. We would test their knowledge of how to use biostatistics and their ability to judge what those statistics actually mean. I deeply relish this study.

What Do The Networks Do?

The Networks declaim:

1. we know the problems
2. we know how to fix the problems
3. all we need is more money.

That is not true. The Networks are given most of their marching orders – each year – by HCFA. And each year the emphasis changes as to what to do and what to report.

The only Networks constant is data collection from the dialysis facilities. The dialysis facilities send hard copy to the Networks. The Network staff type it in and forward it to HCFA and the USRDS. The same data may retyped once, twice, three times!?

This data entry and transfer is the major function and effort performed by the Networks. The OIG Reports failed to examine what the Networks actually do with the majority of their money and time; they need to do so.

No Head of HCFA's ESRD Program

Though I am – probably – as knowledgeable about HCFA and the ESRD program as any, I don't know the person who is charge of the ESRD program. True, in order to send this letter to the inspector general of the Health and Human Services OIG, I have to call several phone numbers in Washington, DC as there was no return address on the OIG Reports. But that was a trivial matter compared to attempting to contact your equal in HCFA. Who is that person? I want to send a copy of this letter to that person in charge of the ESRD program.

As Harry Truman opined, "The buck stops here." And he was right; someone must have ultimate authority and ultimate decision making abilities for his/her department. A person that someone can write to and complain to about grievous faults or errors.

No such person exists for ESRD program at HCFA. The ESRD program at HCFA uses a multi-headed, hydra kind of supervision. Each head snapping at something, unable to deal with what the other heads are doing. There is no chain-of-command, there is no hierarchy of control for the ESRD program. Strangely, there is a czar for kidney transplantation at HCFA. A person who may have such authority as you enjoy. The HCFA kidney transplantation program services comprises both in number of patients and expense, a small fraction of the dialysis ESRD program.

Move Dialysis Facility Data Collection From Networks To HCFA

If the OIG would examine what the Networks actually spent most of their staff time, money, and resources on, they should discover that most Network activity can be assumed by a single, central data collection agency. Put the data collection directly into HCFA. The present Network system of data collection and transfer is very inefficient and error prone. Why is there no OIG study of this important issue?

If the data collection were centralized, the Networks could be held to be accountable for the few other projects they perform. Thus creating a less expensive, much smaller, and hopefully more nimble and focused Network system.

No Data Oversight For Patient Mortality

For the periods that I analyzed the patient mortality, the GMRs, for the eighteen (18) Networks, *each* Network had an *average* GMR *less* than the national average. The USRDS folk agreed with

me that this was a mathematical impossibility and one that strikes at the very heart of oversight, accountability and credibility of data reporting by the Networks to HCFA. The fact that HCFA's personnel failed to understand this very simple error also speaks to HCFA's oversight, accountability and credibility. I reported this impossible mathematics and the findings were ignored.

The OIG Should Do An Independent Investigation

The OIG Reports – probably – used statements from personnel in HCFA to identify the principal problems. All federal agencies will tell you:

1. we know the problems
2. we know how to fix the problems
3. all we need is more money.

The OIG should have done an independent inquiry. For if they did, they would – probably – have heard from me and others who know the major ESRD issues and are not biased by being employed by HCFA or a major dialysis corporation or a powerful drug company such as Amgen. They could have added our input prior to writing their final report. Not to do an independent inquiry is a serious deficiency in the OIG Reports. In the end, the OIG Reports are just an echo of HCFA's various ideas.

Does HCFA Understand ESRD?

If HCFA knows the ESRD problems, how is it that they avoid discussing and focusing on the gold standard of ESRD problems, patient mortality? Why does HCFA pay lip service to it by dealing with less important issues which influence patient mortality!?

HCFA has focused on popular (but less important issues) such as urea removal during dialysis (measured by Kt/V or URR). HCFA has not focused on the issues that cause high patient mortality; which are:

1. high blood pressure (hypertension) and the vascular complications that lead to heart attack, limb amputation, stroke, and then death. Blood pressure was one (1) of the original four (4) variables sampled from dialysis facilities by HCFA. Blood pressure, a gold standard of adequacy of dialysis, was dropped, why?
2. malnutrition, due to protein, calorie and vitamin deficiencies.
3. too much use of Epogen (epoetin), a drug sold only by Amgen in the USA which costs the American tax payor over one billion dollars a year, but costs less per patient if used correctly.
4. gold standards for adequacy of dialysis such as lack of epoetin usage and more dialysis, not less.
5. lack of rehabilitation.
6. lack of rewards for excellence in dialysis care (that's us).

7 reliance on state inspectors who can – maybe – inspect a nursing home but can only comment on the completeness of paper work of an ESRD facility.

8 too short dialysis therapy.

9 refusal to consider funding of dialysis care, such as daily or nocturnal dialysis which is actually less expensive in the long run but not payable under present HCFA guidelines for reimbursement.

10 employment of HCFA physicians and other advisors who have severe, pernicious, and undisclosed conflicts of interest with the deep pocket companies of the dialysis industry.

11 refusal to study dialysis therapy in nursing homes to avoid expensive transportation charges to and from dialysis facilities.

12 lack of competent standards for ESRD personnel education, the second gold standard of ESRD care.

13 too much heparin given pre-dialysis as a single large dose with no monitoring of the complications of that large heparin dose. This problem effects hundreds if not thousands of ESRD patients.

14 lack of any true and valid assessment of patient satisfaction. We did a written questionnaire and study in 1971 (sic). The study showed that the average hemodialysis patients would not disclose their true feelings and assessment of their dialysis treatment. I then individually interviewed these patients.

15 The common thread of their statements was that since the dialysis staff controlled their very life, it would be stupid to make them angry in any way. Even more interesting was that they feared reprisal not from the nephrologist or the director of nursing or the medical director but from the person who handled their needles and their individual machinery; from the person who was immediately involved with them. In the year 2000 that is the Patient Care Technician (PCT), a mostly untrained and uncertified person. No Network has addressed this issue to the best of my knowledge. How can you obtain a valid study of patient satisfaction without removing this fearful bias?

16 lack of standardization of action for patient complaints. Actions which should deal not only with the complaint but would actually attempt to examine if the complaint reflects ESRD care or an ill patient's response to being cranky, poor, angry, and ill.

These are some of the problems, not all of them.

HCFA Can't Analyze GMR, How can they Analyze Epogen Need?

Of the many reasons HCFA has given for not producing and broadcasting a national report of patient survival is that they are unable to fairly calculate that number. HCFA and its contractors are unable to calculate patient survival, this most simple measure, this gold standard, of ESRD care?

But… if they can't fairly calculate patient survival and disseminate it nationally to all dialysis facilities as an open document, how is that they promote Epogen whose effect is supposed to be on patient survival? That is a puzzle.

Thus, HCFA promotes increasing use of Epogen (epoetin) to increase the patient's level of blood hematocrit (percentage of red blood cells to total volume of blood), with the false premise that Epogen can work in the presence of too short dialysis, high patient mortality, malnutrition, hypertension, and multiple drug usage.

We use less Epogen every year and are penalized for our good work. About five percent (5%) of our patients have been taken off of Epogen for months to years and maintain a near normal to super-normal hematocrit.

Adequacy Of Dialysis Is No Epogen

An excellent marker of adequacy of dialysis is a low or lack of Epogen usage, not a high Epogen dose. As you may know Epogen is the single most expensive and revenue producing item in ESRD care. The more you use, the more money you make and can report to your stock-holders. Most private, non-profit, and publically held dialysis companies make upwards of twenty-five percent (25%) of their profit from Epogen.

Kt/V or URR Are Not Equal To Adequacy Of Dialysis

High values for Kt/V or URR do not *equal* the phrase, "adequacy of dialysis." Kt/V or URR are a fraction, a small part of a much larger whole that comprises adequacy of dialysis. Kt/V or URR are only markers of blood urea removal by dialysis. Adequacy of dialysis comprises much more than these two (2) enfeebled numbers. Kt/V or URR have been misrepresented as being equal to adequacy of dialysis by: HCFA, their medical consultants, and by Networks. That is a false premise of great magnitude.

The hemodialysis program of Doctor Bernard Charra that gives his patients their incredible patient survival is not due to urea removal (Kt/V or URR). His patients' annual ninety-five percent (95%) survival is due to blood pressure control and lack of blood pressure medications. Almost all of Doctor Charra ESRD patients have normal blood pressure. His patients do not take the ten (10) or so medications that American ESRD patients must take because of their too short treatment times.

Multiple Drugs, Multiple Complications

It is a medical truism that multiple medications cause multiple patient problems. Medical reports have indicated that up to ten percent (10%) of hospital admissions are due to misuse or misprescription of one (1) or more drugs. What is the statistical probability that a group of patients taking up to ten (10) medications routinely will have a hospitalization rate that is a multiple of that studies findings?

Doctor Scribner Agrees With Doctor Charra

Though one might argue with my penchant for blunt speech, I believe that no one can argue with my educational qualifications or expertise. I trained with Doctor Belding H Scribner, originator and pioneer of chronic hemodialysis therapy. Doctor Scribner has recently written an article with Doctor Charra about this most important marker of adequacy of dialysis, normal blood pressure. Why hasn't HCFA investigated what the father of chronic hemodialysis says is a meaningful marker of excellent dialysis care, normal blood pressure? Why does HCFA persist in attempting to quantify dialysis urea removal as Kt/V and URR; saying that these are the gold standards of dialysis adequacy when they are not?

No Epogen Is an ESRD Gold Standard

An ESRD patient who once required Epogen who now makes enough blood to sustain his/her hematocrit at a normal or super-normal level has a true marker of dialysis adequacy regardless of whatever that patient's URR or Kt/V is.

Marker of Dialysis In-adequacy

A much more potent marker of dialysis *in-adequacy* (than URR or Kt/V) is the pre-dialysis blood urea nitrogen (BUN) coupled with the serum albumin. If both are statistically low, the patient's survival is less than three to six (3 - 6) months unless immediate intervention is taken. What does a low Kt/V or URR mean? Use of the pre-dialysis BUN and serum albumin as laboratory tests of dialysis in-adequacy is more sure and more meaningful as these tests do not depend on formulas, fudge factors, and poor post-dialysis blood drawing techniques.

Abandon Kt/V and URR

Recent data show that the Kt/Vs and URRs have increased without an improvement in patient survival… which is as one would suspect if these tests were fudged and/or not valid for markers to assess adequacy of dialysis. If one is casting around for a better marker for dialysis dose, the *trend* of the pre-dialysis creatinine is much less sensitive to manipulation by inventive dialysis companies. The post-dialysis BUN, which is necessitated by use of Kt/V and URR should be abandoned.

If one were to compare dialysis units with high-quality educated staff with excellent patient care and excellent survival to dialysis units with staff that is slightly or not educated, poor patient care and poor patient survival, one will find that high-quality care is associated with: *lower* URRs or Kt/Vs and *lower* Epogen usage! We can substantiate this – seeming – conundrum if the OIG wishes. A well run dialysis facility will produce valid laboratory and other data; a poorly or indifferently run one will not.

The accuracy of the Kt/V and URR are dependent on accuracy of the post-dialysis BUN. Inaccurate post-dialysis BUN values produce high Kt/V and URRs. We highly recommend that these two (2) so-called determinates of dialysis adequacy either be abandoned or relegated to what their real use is; an estimate of efficiency of a single dialysis treatment. We further recommend that the URR not be used on the Medi-Care bill as it is too easily manipulated upwards.

Is Increasing The Number Of State Surveys Worthwhile?

The initial federal regulations or “Conditions for Coverage” were discussed in 1972, when the ESRD law was passed and before the law took effect in 1973. I know, I was there. By 1976 most dialysis units were struggling to perform dialysis as a chronic therapy. Only a few of us were preoccupied with adequacy of dialysis and long term patient survival. The federal regulations in 1976 were made primarily to more clearly define duties of various personnel, **not to characterize excellence of care**. State surveys should show compliance with these federal regulations. But, these regulations have little correlation to patient survival or excellence of ESRD care.

ESRD Facilities Are Not Nursing Homes

June, 2000 reports from the General Accounting Office (GAO) spoke of how successful it is to inspect nursing homes and then threaten financial reprisal to those nursing homes to comply with the conditions of coverage of federal regulations. There was a logic leap by the GAO that one could apply the same techniques for nursing homes to improve care in ESRD facilities.

There is no correlation between a nursing home and an ESRD facility. To propose one means that one equates the federal “Conditions of Coverage” with excellence in patient care; a very, very false premise. Admittedly this false premise is not in the OIG Reports but both the GAO and OIG Reports speak of punitive measures to force compliance with federal regulations.

Education Of ESRD Personnel, Second Gold Standard

Who would be a passenger in a jet airplane with a pilot who has *never* had formal didactic (lectures) and practicum (hands-on supervision by an expert teacher) training and skills to propel a potentially lethal machine through the air?

Everyday thousands, if not hundreds of thousands of ESRD patients have to entrust their lives to personnel using potential lethal machines who have never had formal didactic and practicum training. The federal regulations, “Conditions of Coverage” define a dialysis Registered Nurse (RN) as a RN who has (paraphrased), “six months experience, working in a dialysis unit.” This is – essentially – no training and is a pale shadow to formal training of any kind. Where are the discussions on ESRD staff education as a serious problem?

The personnel who care for the majority of ESRD patients, the Patient Care Technician (PCT) is not even defined. These people provide care for about seventy-five percent (75%) of all dialysis patients. I estimate that ninety percent (90%) of American PCTs are untrained by the standards we insist on and provide.

With Untrained Staff, Silent Dialysis Deaths Occur

Why is there nothing in yours, HCFA’s, Networks, and state surveyors agendas about education of the ESRD staff? This is a glaring deficiency in analysis of ESRD care. We, by state survey and laboratory data look average as to: patient’s age, high-risk patients, percentage of patients with diabetes mellitus, et cetera. But our patient survival is outstanding.

We educate our staff to know the good care from ignorant or apathic care. We explore every incident of patient or staff misadventure. We take educational, not punitive, actions.

Without knowledgeable staff, patients die silently, “unexpectedly,” and in great numbers. All without notice by anyone in HCFA, the Networks, the state surveyors, and – most poignantly – by those uneducated staff.

If one crashes a jet aircraft, everyone knows about it. Jet crashes are most often due to pilot or other human error. The computerized aircraft machinery has become superb. The same is true in the ESRD field. The dialysis machinery is superb, but their is no standard for training of the:

1. RN
2. PCT
3. Machine Technician

An unskilled and untrained ESRD care giver can cause the death, directly or indirectly, of many ESRD patients and none of this is ever noticed by HCFA, the state surveyors, or the Networks.

Untrained State Surveyors

Did you know that state surveyors, as best as I can discover, require no formal training to survey an ESRD facility? When I was on the Board of Directors/Medical Review Board of Network #18, I proposed we set up a series of workshops for these state surveyors. Since the state surveyors are paid directly by HCFA, they did what is normal… they refused.

State Laws And Due Diligence

The OIG Reports report speak highly of recent legislation in Texas and how it has “improved care….” The text is an insult to us in California where we had similar if not better legislation *at least a decade* before Texas. In the lauding of the accomplishments of recent Texas law, your staff failed to point out that what Texas did about 1999, pass a law certifying PCTs, we did in California in 1984.

The fact that your staff is unaware of the many California laws which preceded and served as examples and templates for Texas and other states probably speaks to either naiveté or lack of due diligence on the part of your staff. This is said not to detract from what was done in Texas but to note that the state law form an uneven patch-work of ESRD laws and regulation which makes the cost of doing ESRD business very high in California, and very low in Illinois and Texas.

The GMR, and dialysis adequacy, should be related to costs of complying with state regulations and law. In Illinois, a dialysis station can occupy fifty (50) square feet, in California, it is one-hundred and ten (110) square feet. It costs much more to build and maintain a dialysis unit in California which requires nine (9) separate rooms or areas to support the dialysis patient care area; not so in Illinois. In Illinois, there is no standard of training for PCTs, in California, there is. Very vital issues not even dreamed of by HCFA or considered by your staff. I know the

OIG's staff includes accountants, why hasn't there been a cost-benefit analysis of these state laws on the care of the ESRD patient?

Untrained PCTs

Except for California and very recently Texas, very few states have laws or regulations which speak to the training or certification of those individuals who do the majority of care for the ESRD patients, the PCT. Why is that? Why is not education the first pillor of the ESRD house? Why is not formal education of medical and nursing staff the cornerstone of the HCFA mansion?

Why isn't a national standard for education for ESRD staff and the state surveyors one of the first steps in improving ESRD care?

Summary

Finally, a summary of this eleven (11) page letter can be done as a short aphorism shown in the box below. It has been formatted so that it may be cut out and put into the wallets of any who wants a reminder of what I have written. A pithy distillation of the state of American health-care. A view and a reminder of the present state of affairs. An aphorism that can speak to all American care givers.

Yours for better American ESRD health-care,

John R De Palma, MD, FACP
CEO Hemodialysis, Inc