Final Order No. DOH-07-0297-S-MQA
FILED DATE - 2/28/07
Department of Health
By: Rachel Bell
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF MEDICINE

DEPARTMENT OF HEALTH,

Petitioner,

vs.

DOH CASE NO.: 2004-07954
2004-14621
LICENSE NO.: ME0078304

SERGE VILVAR, M.D.,

Respondent.
_____/

FINAL ORDER

THIS CAUSE came before the BOARD OF MEDICINE (Board) pursuant to Sections 120.569 and 120.57(4), Florida Statutes, on February 3, 2007, in Orlando, Florida, for the purpose of considering a Settlement Agreement (attached hereto as Exhibit A) entered into between the parties in this cause. Upon consideration of the Settlement Agreement, the documents submitted in support thereof, the arguments of the parties, and being otherwise fully advised in the premises,

IT IS HEREBY ORDERED AND ADJUDGED that the Settlement Agreement as submitted be and is hereby approved and adopted in toto and incorporated herein by reference with the following clarifications:

1. The costs set forth in Paragraph 4 of the Stipulated Disposition shall be set at $10,000.

2. The lecture required by Paragraph 9 of the Stipulated Disposition shall be clarified to require the subject of said lecture to be approved by the Board's Probation Committee.

Accordingly, the parties shall adhere to and abide by all the terms and conditions of the Settlement Agreement as clarified above.

This Final Order shall take effect upon being filed with the Clerk of the Department of Health.

DONE AND ORDERED this 15 day of FEBRUARY, 2007.

BOARD OF MEDICINE

Larry McPherson, Jr., Executive Director
for ROBERT CLINE, M.D., Vice-Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by U.S. Mail to SERGE VILVAR, M.D., 3501 SW 145 Avenue, Miramar, Florida 33027; and 1380 North Miami Gardens Drive, Suite 242, North Miami Beach, Florida 33179; to Wilson Jerry Foster, Esquire, 1342 Timberlane Road, Suite 101-A, Tallahassee, Florida 32312; and by interoffice delivery to John Terrel, Department of Health, 4052 Bald Cypress

Way, Bin #C-65, Tallahassee, Florida 32399-3253 this 21st day of February, 2007.

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Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v.

DOH Case No. 2004-07954
DOH Case No. 2004-14621

SERGE VILVAR, M.D.,

Respondent.
_____/

SETTLEMENT AGREEMENT

Serge Vilvar, M.D., referred to as the "Respondent," and the Department of Health, referred to as "Department" stipulate and agree to the following Agreement and to the entry of a Final Order of the Board of Medicine, referred to as "Board," incorporating the Stipulated Facts and Stipulated Disposition in this matter.

Petitioner is a state agency charged with regulating the practice of medicine pursuant to Section 20.43, Florida Statutes, and Chapter 456, Florida Statutes, and Chapter 458, Florida Statutes.

STIPULATED FACTS

1. At all times material hereto, Respondent was a licensed physician in the State of Florida having been issued license number ME 78304.

2. The Department charged Respondent with an Amended Administrative Complaint that was filed and properly served upon Respondent with violations of Chapter 458, Florida Statutes, and the rules adopted pursuant thereto. A true and correct copy of the Administrative Complaint is attached hereto as Exhibit A.

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3. Respondent neither admits nor denies the allegations of fact contained in the Administrative Complaint for purposes of these proceedings only.

STIPULATED CONCLUSIONS OF LAW

1. Respondent admits that, in his capacity as a licensed physician, he is subject to the provisions of Chapters 456 and 458, Florida Statutes, and the jurisdiction of the Department and the Board.

2. Respondent admits that the facts alleged in the Administrative Complaint, if proven, would constitute violations of Chapter 458, Florida Statutes, as alleged in the Administrative Complaint.

3. Respondent agrees that the Stipulated Disposition in this case is fair, appropriate and acceptable to Respondent.

STIPULATED DISPOSITION

1. **Suspension Language:** Respondent's license shall be suspended for a period of six (6) months effective on the date of the filing of the Final Order incorporating the terms adopts the terms of this Agreement.

2. **Restriction on Practice:** -

a. Respondent's practice is permantley restricted in that Respondent may not prescribe, administer or engage in any practice in which intravenous Rh_o (D) Immune Globulin (Human) is administered.

b. Respondent's practice is restricted in that Respondent may not treat patients for the HIV/AIDS condition until permitted by the Board of Medicine.

3. **Fine** - The Board of Medicine shall impose an administrative fine of $50,000 against the license of Respondent, to be paid by Respondent to the Department of Health, HMQAMS/Client Services, Post Office Box 6320, Tallahassee, Florida 32314-6320, Attention: Board of Medicine Compliance Officer, within 180 days from the date of the reinstatement of Respondent's license to practice medicine as set out in the Final Order accepting this Agreement. All fines shall be paid by check or money order. The Board office does not have the authority to change the terms of payment of any fine imposed by the Board.

RESPONDENT ACKNOWLEDGES THAT THE TIMELY PAYMENT OF THE FINE IS HIS/HER LEGAL OBLIGATION AND RESPONSIBILITY AND RESPONDENT AGREES TO CEASE PRACTICING IF THE FINE IS NOT PAID AS AGREED TO IN THS SETTLEMENT AGREEMENT, SPECIFICALLY: IF WITHIN 180 days OF THE DATE OF THE RESTATEMENT OF RESPONDENT'S LICENSE TO PRACTICE MEDICINE, RESPONDENT HAS NOT RECEIVED WRITTEN CONFIRMATION THAT THE FULL AMOUNT OF THE FINE HAS BEEN RECEIVED BY THE BOARD OFFICE, RESPONDENT AGREES TO CEASE PRACTICE UNTIL SUCH WRITTEN CONFIRMATION IS RECEIVED BY RESPONDENT FROM THE BOARD.

4. **Reimbursement Of Costs** - Pursuant to Section 456.072, Florida Statutes, Respondent agrees to pay the Department for any administrative costs incurred in the investigation and preparation of this case. Such costs exclude the costs of obtaining supervision or monitoring of the practice, the cost of quality

assurance reviews, and the Board's administrative cost directly associated with Respondent's probation, if any. The agreed upon amount of Department costs to be paid in this case includes but shall not exceed $10,000. Respondent will pay costs to the Department of Health, HMQAMS/Client Services, P.O. Box 6320, Tallahassee, Florida 32314-6320, Attention: Board of Medicine Compliance Officer within thirty-days (30) from the date of filing of the Final Order in this cause. Any post-Board costs, such as the costs associated with probation, are not included in this agreement.

RESPONDENT ACKNOWLEDGES THAT THE TIMELY PAYMENT OF THE COSTS IS HIS/HER LEGAL OBLIGATION AND RESPONSIBILITY AND RESPONDENT AGREES TO CEASE PRACTICING IF THE COSTS ARE NOT PAID AS AGREED TO IN THIS SETTLEMENT AGREEMENT, SPECIFICALLY: IF WITHIN 45 DAYS OF THE DATE OF FILING OF THE FINAL ORDER, RESPONDENT HAS NOT RECEIVED WRITTEN CONFIRMATION THAT THE FULL AMOUNT OF THE COSTS NOTED ABOVE HAS BEEN RECEIVED BY THE BOARD OFFICE, RESPONDENT AGREES TO CEASE PRACTICE UNTIL SUCH WRITTEN CONFIRMATION IS RECEIVED BY RESPONDENT FROM THE BOARD.

5. **Laws And Rules Course** - Respondent shall complete the Laws and Rules Course, administered by the Florida Medical Association, within one (1) year of the date of filing of the Final Order of the Board. In addition, Respondent shall submit documentation in the form of certified copies of the receipts, vouchers,

certificates, or other papers, such as physician's recognition awards, documenting completion of this medical education course within one (1) year of the date of filing of the Final Order incorporating this Agreement. **All such documentation shall be sent to the Board of Medicine, regardless of whether some or any of such documentation was previously provided during the course of any audit or discussion with counsel for the Department. These hours shall be in addition to those required for renewal of licensure. Unless otherwise approved by the Board, said continuing medical education courses shall consist of a live, lecture format.**

6. **Continuing Medical Education:**

(A). **Records Course (CME)** - Respondent shall complete the course, "Quality Medical Record Keeping for Health Care Professionals," sponsored by the Florida Medical Association, or a Board-approved equivalent, within one year of the date of filing of the Final Order.

(B). **Treatment of HIV Course (CME)** : Within one year of the date of the filing of a Final Order in this cause, Respondent shall attend five (5) hours of Continuing Medical Education (CME) in treatment of HIV-positive patients. Respondent shall first submit a written request to the Probation Committee for approval prior to performance of said continuing medical education course(s). Respondent shall submit documentation in the form of certified copies of the receipts, vouchers, certificates, or other papers, such as physician's recognition

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awards, documenting completion of this medical course within one (1) year of the date of filing of the Final Order.

(C). **"Risk Management"** - Respondent shall complete five (5) hours of Continuing Medical Education in "Risk Management" within one (1) year of the date of filing of the Final Order. Respondent shall first submit a written request to the Probation Committee for approval prior to performance of said continuing medical education course(s). However, the Board has approved five (5) hours of risk management continuing education for attending the first day of a full Board of Medicine meeting.

(D). **Documentation**: Respondent shall submit documentation in the form of certified copies of the receipts, vouchers, certificates, or other papers, such as physician's recognition awards, documenting completion of these medical courses within one (1) year of the date of filing of the Final Order in this matter. All such documentation shall be sent to the Board of Medicine, regardless of whether some or any of such documentation was provided previously during the course of any audit or discussion with counsel for the Department. These hours shall be in addition to those hours required for renewal of licensure. Unless otherwise approved by the Board, said continuing medical education course(s) shall consist of a formal, live lecture format.

7. **Community Service** - Respondent shall perform 50 hours of community service, within one year of the date of the reinstatement of Respondent's license to practice medicine following the suspension of his license.

Community Service shall be defined as the delivery of medical services directly to patients, or the delivery of other volunteer services in the community, without fee or cost to the patient or the entity, for the good of the people of the State of Florida. Community service shall be performed outside the physician's regular practice setting. Respondent shall submit a written plan for performance and completion of the community service to the Probation Committee for approval prior to performance of said community service. Affidavits detailing the completion of community service requirements shall be filed with the Board as required by the Probation Committee.

8. **Quality Assurance Consultation/Risk Management Assessment** - An independent, certified risk manager will review Respondent's current practice within sixty (60) days of the date of filing of the Final Order. Specifically, this independent consultant shall review the office procedures employed at Respondent's practice. This consultant will prepare a report addressing Respondent's practice. This report will include suggested improvements of the quality assurance of Respondent's practice. Respondent will submit this report, as well as documentation that demonstrates compliance with the suggestions enumerated in the report, to the Probation Committee. Respondent shall bear the cost of such consultation and any necessary or appropriate follow-up consultation.

9. **Lecture/Seminar** - During the next six (6) months following the filing date of a Final Order in this case, Respondent shall present a one (1) hour lecture/seminar on. The lecture/seminar shall be presented to medical staff at an

approved medical facility. Respondent shall submit a written plan to the Board for approval prior to performance of said lecture/seminar. Respondent shall also provide written documentation to the Board that said lecture/seminar has been completed within six months of the date of filing of the Final Order in this case. Said documentation shall consist of a letter from the Risk Manager of the approved medical facility indicating that the lecture/seminar has been completed.

10. **Probation Language** - Effective on the date on which Respondent's suspension is completed, Respondent's license to practice medicine shall be placed on probation for a period of one (1) year. The purpose of probation is not to prevent Respondent from practicing medicine. Rather, probation is a supervised educational experience designed by the Board to make Respondent aware of certain obligations to Respondent's patients and the profession and to ensure Respondent's continued compliance with the high standards of the profession through interaction with another physician in the appropriate field of expertise. To this end, during the period of probation, Respondent shall comply with the following obligations and requirements:

(A) **Restrictions During Probation** - During the period of probation, Respondent's license shall be restricted as follows:

i. **Indirect Supervision** - Respondent shall engage in family practice only under the indirect supervision of a Board-approved physician, hereinafter referred to as the "monitor", whose responsibilities are set by the Board. Indirect supervision does not

require that the monitor practice on the same premises as Respondent, however, the monitor shall practice within a reasonable geographic proximity to Respondent, which shall be within 20 miles unless otherwise provided by the Board and shall be readily available for consultation. The monitor shall be Board Certified in Respondent's family practice specialty area unless otherwise provided by the Board. In this regard, Respondent shall allow the monitor access to Respondent's family practice medical records, calendar, patient logs or other documents necessary for the monitor to supervise Respondent as detailed below.

ii. **Required Supervision:**

a) Pursuant to indirect monitoring of Respondent's practice, Respondent shall not practice family medicine without an approved monitor/supervisor, as specified by the Agreement, unless otherwise ordered by the Board.

b) The monitor/supervisor must be a licensee under Chapter 458, Florida Statutes, in good standing and without restriction or limitation on his license. In addition, the Board may reject any proposed monitor/supervisor on the basis that he has previously been subject to any disciplinary action against his medical license in this or any other jurisdiction, is currently under investigation, or is the subject of a pending disciplinary

action. The monitor/supervisor must be actively engaged in the same or similar specialty area unless otherwise provided by the Board and be practicing within a reasonable distance of Respondent's practice, a distance of twenty (20) miles unless otherwise specifically provided for in the Settlement Agreement. The Board may also reject any proposed monitor/supervisor for good cause shown.

iii. **Approval Of Monitor/Supervisor:**

a) **Temporary Approval** - The Board confers authority on the Chairman of the Probation Committee to temporarily approve Respondent's monitor/supervisor. To obtain this temporary approval, Respondent shall submit to the Chairman of the Probation Committee the name and curriculum vitae of the proposed monitor/supervisor at the time this agreement is considered by the Board. **Once a Final Order adopting the Agreement is filed, Respondent shall not practice medicine without an approved monitor/supervisor. Temporary approval shall only remain in effect until the next meeting of the Probation Committee.**

b) **Formal Approval** - Respondent shall have the monitor/supervisor with Respondent at Respondent's first

probation appearance before the Probation Committee. Prior to the consideration of the monitor/supervisor by the Probation Committee, Respondent shall provide to the monitor/supervisor a copy of the Administrative Complaint and Final Order in this case. Respondent shall submit a current curriculum vita and a description of current practice from the proposed monitor/supervisor to the Board office no later than fourteen (14) days before Respondent's first scheduled probation appearance. Respondent's monitor/supervisor shall also appear before the Probation Committee at such other times as directed by the Probation Committee. It shall be Respondent's responsibility to ensure the appearance of the monitor/supervisor as directed. Failure of the monitor/supervisor to appear as directed shall constitute a violation of the terms of this Settlement Agreement and shall subject Respondent to disciplinary action.

iv. **Change In Monitor/Supervisor** - In the event that Respondent's monitor/supervisor is unable or unwilling to fulfill the responsibilities of a monitor/supervisor as described above, Respondent shall immediately advise the Probation Committee of this fact. Respondent shall immediately submit to the Chairman of the Probation Committee the name of a temporary

monitor/supervisor for consideration. Respondent shall not practice pending approval of this temporary monitor/supervisor by the Chairman of the Probation Committee. Furthermore, Respondent shall make arrangements with his temporary monitor/supervisor to appear before the Probation Committee at its next regularly scheduled meeting for consideration of the monitor/supervisor by the Probation Committee. Respondent shall only practice under the auspices of the temporary monitor/supervisor (approved by the Chairman) until the next regularly scheduled meeting of the Probation Committee at which the issue of the Probation Committee's approval of Respondent's new monitor/supervisor shall be addressed.

v. Responsibilities of the Monitor/Supervisor - The Monitor shall:

a) Review 20 percent of Respondent's active patient records (excluding psychiatric records) at least once every quarter for the purpose of ascertaining that Respondent is appropriately diagnosing and proposing appropriate treatment, adequately documenting patient treatment plans, and monitoring patients' responses to ongoing treatment. The monitor shall go to Respondent's office once every quarter and

shall review Respondent's calendar or patient log and shall select the records to be reviewed.

b) Submit reports on a quarterly/semiannual basis, in affidavit form, which shall include:

1) A brief statement of why Respondent is on probation;

2) A description of Respondent's practice (type and composition);

3) A statement addressing Respondent's compliance with the terms of probation;

4) A brief description of the monitor's relationship with Respondent;

5) A statement advising the Probation Committee of any problems which have arisen; and

6) A summary of the dates the monitor went to Respondent's office, the number of records reviewed, and the overall quality of the records reviewed, and the dates Respondent contacted the monitor pursuant to subsection c), 3), above.

c) Report immediately to the Board any violations by Respondent of Chapters 456 or 458, Florida Statutes, and the rules promulgated thereto.

d) Respondent's monitor shall appear before the Probation Committee at the first meeting of said committee following commencement of the probation, and at such other times as directed by the Committee. It shall be Respondent's responsibility to ensure the appearance of Respondent's monitor to appear as requested or directed. If the approved monitor fails to appear as requested or directed by the Probation Committee, **Respondent shall immediately cease practicing medicine until such time as the approved monitor or alternate monitor appears before the Probation Committee.**

vi. **Reports From Respondent** - Respondent shall submit quarterly/semiannual reports, in affidavit form, the contents of which may be further specified by the Board, but which shall include:

a) A brief statement of why Respondent is on probation;

b) A description of practice location;

c) A description of current practice (type and composition);

d) A brief statement of compliance with probationary terms;

e) A description of the relationship with monitoring physician;

f) A statement advising the Board of any problems which have arisen; and

g) A statement addressing compliance with any restrictions or requirements imposed.

vii. **Continuity of Practice:**

a) **Tolling Provisions** - In the event Respondent leaves the State of Florida for a period of thirty days or more or otherwise does not engage in the active practice of medicine in the State of Florida, then certain provisions of Respondent's probation (and only those provisions of the probation) shall be tolled as enumerated below and shall remain in a tolled status until Respondent returns to active practice in the State of Florida:

1) The time period of probation shall be tolled;

2) The provisions regarding supervision whether direct or indirect by another physician, and

required reports from the monitor/supervisor shall be tolled;

3) The provisions regarding preparation of investigative reports detailing compliance with this Settlement Agreement shall be tolled; and

4) Any provisions regarding community service shall be tolled.

b) **Active Practice** - In the event that Respondent leaves the active practice of medicine for a period of one year or more, the Board may require Respondent to appear before the Board and demonstrate his ability to practice medicine with skill and safety to patients prior to resuming the practice of medicine in this State.

(8) Obligations/Requirements Of Probation - During the period of probation, Respondent shall comply with the following obligations and requirements:

1. Respondent shall appear before the Probation Committee of the Board of Medicine at the first Committee meeting after probation commences, at the last meeting of the Committee preceding scheduled termination of the probation, and at such other times as requested by the Committee. Respondent shall be noticed by the Board staff of the date, time and place of the Committee meeting at which Respondent's

appearance is required. Failure of Respondent to appear as requested or directed or failure of Respondent to comply with any of the terms of this agreement shall be considered a violation of the terms of this Agreement, and shall subject Respondent to disciplinary action.

STANDARD PROVISIONS

11. **Appearance**: Respondent is required to appear before the Board at the meeting of the Board where this Agreement is considered.

12. **No force or effect until final order** - It is expressly understood that this Agreement is subject to the approval of the Board and the Department. In this regard, the foregoing paragraphs (and only the foregoing paragraphs) shall have no force and effect unless the Board enters a Final Order incorporating the terms of this Agreement.

13. Addresses - Respondent must keep current residence and practice addresses on file with the Board. Respondent shall notify the Board within ten (10) days of any changes of said addresses.

14. Future Conduct - In the future, Respondent shall not violate Chapter 456, 458 or 893, Florida Statutes, or the rules promulgated pursuant thereto, or any other state or federal law, rule, or regulation relating to the practice or the ability to practice medicine. Prior to signing this agreement, the Respondent shall read Chapters 456, 458 and 893 and the Rules of the Board of Medicine, at Chapter 64B8, Florida Administrative Code.

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15. **Violation of terms considered** - It is expressly understood that a violation of the terms of this Agreement shall be considered a violation of a Final Order of the Board, for which disciplinary action may be initiated pursuant to Chapters 456 and 458, Florida Statutes.

16. **Purpose of Agreement** - Respondent, for the purpose of avoiding further administrative action with respect to this cause, executes this Agreement. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to or in conjunction with consideration of the Agreement. Respondent agrees to support this Agreement at the time it is presented to the Board and shall offer no evidence, testimony or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Agreement not be accepted by the Board, it is agreed that presentation to and consideration of this Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration or resolution of these proceedings.

17. **No preclusion of additional proceedings** - Respondent and the Department fully understand that this Agreement and subsequent Final Order incorporating same will in no way preclude additional proceedings by the Board and/or the Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint attached as Exhibit A.

18. **Waiver of attorney's fees and costs** - Upon the Board's adoption of this Agreement, the parties hereby agree that with the exception of costs noted above, the parties will bear their own attorney's fees and costs resulting from prosecution or defense of this matter. Respondent waives the right to seek any attorney's fees or costs from the Department and the Board in connection with this matter.

19. **Waiver of further procedural steps** - Upon the Board's adoption of this Agreement, Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of or to otherwise challenge or contest the validity of the Agreement and the Final Order of the Board incorporating said Agreement.

SIGNED this 5TH day of JANUARY, 2006.07

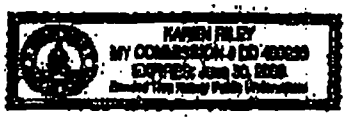
Serge Vilvar, M.D.

Before me, personally appeared SERGE VILVAR, whose identity is known to me by FL DR LIC (type of identification) and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 5TH day of JANUARY, 2006.07

NOTARY PUBLIC

My Commission Expires:



APPROVED this 5th day of JANUARY, 2007.

M. Rony Francois, M.D., M.S.P.H., Ph.D.
Secretary, Department of Health

By: Attorney
Assistant General Counsel
Department of Health

**** If a priority one case, use the signature line for the Deputy GC:

By: Mari M. Presley
Deputy General Counsel
Department of Health

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STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2004-14621**

SERGE VILVAR, M.D.

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Medicine against Respondent, Serge Vilvar, M.D., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of medicine pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 458, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed physician within the state of Florida having been issued license number ME 78304.

3. Respondent's address of record is 1380 North Miami Gardens Drive, Suite 242, North Miami Beach, FL 33179.

4. Respondent is board certified in Psychiatry, Neurology, and Family Practice.

5. On or about October 7, 2002, the Respondent began treating Patient A.M. for an HIV infection.

6. The Respondent initially advised Patient A.M. to continue with his current medications and to return after he had received diagnostic blood work.

7. The Respondent began Patient A.M. on IVIG infusion therapy on October 11, 2002. The therapy was recommended to help prevent opportunistic infections in Patient A.M.

8. After January 17, 2003, the Respondent stopped documenting Patient A.M.'s physical examinations and complaints. After January 17, 2003, all medical records consist only of infusion therapy records, which provide no documented examinations or evaluations of Patient A.M.'s condition or any mention of his diagnostic tests.

9. The Respondent also continued to perform the IVIG treatment on Patient A.M. without any type of diagnostic blood work to determine the effectiveness of or to determine any potential complications from Patient A.M.'s IVIG treatment.

10. From on or about April 2, 2003 until on or about August 27, 2003 Patient A.M. continued receiving the IVIG therapy with no records documenting his physical examination nor evaluating his diagnostic tests.

11. On or about January 17, 2003 the Respondent documented that Patient A.M. suffered from anemia yet never followed up with any treatment for that condition. The Respondent did not address any of Patient A.M.'s abnormal blood tests, which were completed on or about April 17, 2003; April 21, 2003; and August 13, 2003.

COUNT I

12. Petitioner re-alleges and incorporates paragraphs one (1) through eleven (11) as if fully set forth herein.

13. Section 458.331(1)(t), Florida Statutes (2002), provides that gross and repeated malpractice or the failure to practice

medicine with that level of care, skill and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances, constitute grounds for disciplinary action by the Board of Medicine.

14. Respondent failed to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar circumstances, in one or more of the following ways:

(a) By failing to document his evaluations and observations regarding Patient A.M.'s HIV infection;

(b) By not documenting that Patient A.M. was not receiving any type of similar treatment elsewhere;

(c) By failing to evaluate Patient A.M's abnormal blood tests and offer an appropriate treatment or referral;

(d) By failing to monitor and evaluate Patient A.M.'s anemia and provide an appropriate treatment or referral.

15. Based on the foregoing, Respondent violated Section 458.331(1)(t), Florida Statutes (2003), by failing to practice medicine

with that level of care, skill and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances.

COUNT II

16. Petitioner re-alleges and incorporates paragraphs one (1) through eleven (11) as if fully set forth herein.

17. Section 458.331(1)(m), Florida Statutes (2003), provides that failing to keep legible, medical records that identify the licensed physician or the physician extender and supervising physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that justify the course of treatment of the Patient, including but not limited to, Patient histories; examination results; test results, records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

18. That Respondent failed to maintain medical records that documented the examinations of Patient A.M., failed to maintain any justification for the ongoing IVIG treatment, and to document and/or address the abnormal test results of Patient A.M.

19. Based upon the foregoing, Petitioner respectfully requests that the Board of Medicine enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 31st **day of** May, **2006.**

M. Rony Francois, M.D., M.S.P.H., Ph.D.
Secretary, Department of Health

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Shannon McKeever
DATE 5-31-06

Warren James Pearson
Assistant General Counsel
Florida Bar No. 0711578
4052 Bald Cypress Way-Bin C-65
Tallahassee, Florida 32399-3265
(850) 245-4640 ext 8141
(850) 245-4681 FAX

PCP: May 26, 2006

PCP MEMBERS: El-Behai, Farmer

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2004-07954**

SERGE VILVAR, M.D.,

RESPONDENT.
_____/

AMENDED ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health, by and through its undersigned counsel, and files this Amended Administrative Complaint before the Board of Medicine against Respondent, Serge Vilvar, M.D., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of medicine pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 458, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed physician within the state of Florida, having been issued license number ME 78304.

3. Respondent's address of record is 1380 North Miami Gardens Drive, Suite 242, North Miami Beach, Florida 33179.

4. Respondent is board certified in family practice and in psychiatry.

5. At all times material hereto, Respondent practiced medicine at 601 SW 57 Avenue, Miami, Florida 33144.

6. At all times material hereto, Respondent provided intravenous WinRh$_o$ SDF (WinRh$_o$), a brand name for Rh$_o$ (D) Immune Globulin (Human), treatments to at least 15 Medicare/Medicaid patients that had been diagnosed with human immunodeficiency virus (HIV) or with Hepatitis C. Respondent prescribed and administered the same dose of WinRh$_o$ (250 IU/kg) to 14 of the 15 patients and did not alter the dosage throughout the treatments. These treatments were billed to Medicare under Respondent's Medicare provider and crossed over to Medicaid under Respondent's Medicaid provider number and the treatments were billed as medically necessary due to a diagnosis of primary

thrombocytopenia. Each treatment was billed as lasting one hour and ten minutes. Respondent billed Medicaid/Medicare $3,000,000 for infusion therapy.

7. Medicare is a system of health insurance for the aged and disabled. The Department of Health and Human Services ("HHS"), through the Health Care Financing Administration ("HCFA"), administers the Medicare program. Medicare Part B covers the costs incurred by eligible beneficiaries for certain medical services. The Medicare program reimburses only care that is reasonable and necessary for the treatment or diagnosis of illness or injury.

8. Medicaid is a federally-funded, state-run program that provides medical assistance for individuals and families with limited incomes and resources. The Agency for Health Care Administration (AHCA) administers the Florida Medicaid program. Medicaid reimburses only care that is medically necessary.

9. Medicare reimbursement is not permitted for unnecessary or unreasonable care and services.

10. The Agency for Health Care Administration, Office of Medicaid Program Integrity (MPI), audits and regulates the payment of funds to Medicaid providers for services rendered to Medicaid recipients in the state of Florida.

11. MPI requested that Respondent provide patient records in support of his billing Medicaid for infusion therapy. MPI requested the patient records several times and Respondent failed to provide MPI with documentation supporting the medical necessity of the infusion therapy for patients. As a result, Medicaid terminated Respondent as a Medicaid provider.

GENERAL ALLEGATIONS

12. Thrombocytopenia is any disorder in which there are an abnormally small number of platelets in the circulating blood. Platelets are found in the bloodstream and are needed for blood to clot properly. Thrombocytopenia occurs when there is a quantity of platelets below the normal range of 140,000 to 440,000 platelets per micro liter (x 10^{-6}/Liter) of blood. The treatment for thrombocytopenia varies with its cause and severity.

13. Primary thrombocytopenia (also known as essential thrombocytopenia) is a condition of underproduction of platelets without a recognizable cause. Primary thrombocytopenia is a slowly progressing disorder caused by undergrowth of a type of cell that is a precursor of blood cells. Usually the disorder affects people in middle age. Bleeding can occur from the gastrointestinal tract, respiratory system, urinary tract, or skin.

14. Idiopathic thrombocytopenia purpura (ITP) is a bleeding disorder characterized by too few platelets in the blood. This is because platelets are being destroyed by the immune system. Idiopathic means the exact cause of the disease is unknown. (Because more is being learned about the autoimmune nature of the disease, it is sometimes called immune thrombocytopenic purpura.) The disease occurs when immune system cells, called lymphocytes, produce antibodies against platelets. Platelets are necessary for normal blood clotting. They clump together to plug small holes in damaged vessels. The presence of antibodies on platelets leads to their destruction in the spleen. A characteristic skin rash, easy bruising, abnormal menstrual bleeding, or sudden and severe loss of blood from the gastrointestinal tract may occur.

15. Secondary thrombocytopenia is a disorder that occurs because of some other specific illness, such as HIV, or a specific medication's side effects which reduces the number of platelets in the blood.

16. HIV is a retrovirus. HIV integrates its RNA into the DNA of human cells and replicates, causing infection. As the virus replicates, it infects healthy cells, spreading the infection throughout the body. HIV easily spreads through billions of cells in the body if replication is not halted.

17. WinRh$_o$ SDF (WinRh$_o$), a brand name for Rh$_o$ (D) Immune Globulin (Human), is used to increase platelet counts in Rh positive, non-splenectomized adults with chronic ITP.

18. WinRh$_o$ must be used with caution in patients with low hemoglobin levels due to the risk of increasing the severity of the anemia.

19. The frequency and dose of WinRh$_o$ should be determined by the physician based on the patient's clinical response to treatment by regularly assessing platelet counts, red cell counts, hemoglobin, and reticulocyte levels.

20. WinRh$_o$ is not recommended for adults with HIV related thrombocytopenia, unless the patient is bleeding excessively or preparing for surgery and the patient's platelet counts are less than 30,000.

21. Following administration of WinRh$_o$ SDF, ITP patients should be regularly monitored for signs and/or symptoms of intravascular hemolysis (IVH), clinically compromising anemia, and renal insufficiency.

22. In patients with HIV related thrombocytopenia, the recommended course of treatment is appropriate medication for HIV. Long-term administration of WinRh$_o$ infusion therapy is not a recommended course of treatment.

23. In the treatment of ITP, WinRh$_o$ SDF must be administered via intravenous route. An initial dose of 250 IU/kg body weight is recommended for the treatment of ITP.

24. In the treatment of ITP, if subsequent therapy is required to elevate platelet counts, an intravenous dose of 125 to 300 IU/kg body weight of WinRh$_o$ SDF is recommended.

SPECIFIC ALLEGATIONS PERTAINING TO PATIENTS

Patient DJ

25. In February of 2002, Patient DJ, an HIV positive male, first presented to Respondent for a physical evaluation.

26. Respondent's medical records indicated that DJ was in "no acute distress." In addition, Respondent's records contain blood test results dated December 4, 5, and 6 of 2001, indicate platelet counts of 265,000,[1] 210,000, and 196,000 respectively. These platelet counts are well within the normal range.

27. Beginning on or about March 22, 2002, and continuing through on or about August 18, 2003, Respondent prescribed and administered WinRh$_o$ to DJ 193 times. The treatments were generally administered twice a week.

[1] Any reference to platelet count refers to the platelets per microliter.

28. On or about January 10, 2003, a blood test indicated Patient DJ had a platelet count of 158,000 thousand.

29. On or about March 3, 2003, a blood test indicated Patient DJ had a platelet count of 235,000.

30. On or about July 30, 2003, a blood test indicated Patient DJ had a platelet count of 201,000.

31. Respondent's medical records for Patient DJ's do not support a diagnosis of primary thrombocytopenia or ITP and the records do not provide medical justification for the repeated intravenous infusion of $WinRh_o$.

32. At no time did Patient DJ exhibit any of the conditions indicated as appropriate for $WinRh_o$ infusion therapy. Patient DJ's thrombocytopenia was secondary to HIV.

33. Patient DJ did not exhibit any active bleeding and there was no impending surgery.

34. Respondent's medical records for Patient DJ indicate that he initiated the administration of infusion therapy when the patient's platelet count was normal and continued the therapy without assessment of platelet counts, red cell counts, hemoglobin, and reticulocyte levels.

35. Respondent did not adequately monitor Patient DJ following WinRh$_o$ infusion therapy for known complications such as signs and/or symptoms of intravascular hemolysis, clinically compromising anemia, and renal insufficiency.

Patient DMJ

36. On or about May 5, 2003, Patient DMJ, an HIV positive male with Hepatitis C, presented to Respondent for a physical evaluation. DMJ did not present with any active bleeding or impending surgery.

37. On May 5, 2003, a blood test indicated that Patient DMJ had a platelet count of 81,000.

38. Beginning on or about May 7, 2003, and continuing through November 12, 2003, Respondent prescribed and administered WinRh$_o$ to DMJ 80 times. The treatments were generally administered twice a week.

39. The only other blood test in Respondent's records for Patient DMJ is dated September 10, 2003. This test indicates that Patient DMJ's platelet count had dropped to 55,000 (four months into WinRh$_o$ treatment). The blood test also indicated that DMJ's potassium was high and the viral loads were high.

40. DMJ's medical records do not indicate that Respondent addressed the high potassium or the high viral loads.

41. Respondent's medical records for Patient DMJ do not support a diagnosis of primary thrombocytopenia or ITP. Patient DMJ's thrombocytopenia was secondary to HIV.

42. At no time did Patient DMJ exhibit any of the conditions indicated as appropriate for repeated intravenous infusion of WinRh$_o$.

43. Respondent's medical records for Patient DMJ indicate that he initiated the administration of infusion therapy even though the platelet counts and the patient's condition did not warrant the therapy and continued the therapy without adequate assessment platelet counts, red cell counts, hemoglobin, and reticulocyte levels.

44. Respondent did not adequately monitor Patient DMJ following WinRh$_o$ infusion therapy for known complications such as signs and/or symptoms of intravascular hemolysis (IVH), clinically compromising anemia, and renal insufficiency.

Patient AM

45. In October of 2002, Patient AM (formerly known as AW), an HIV positive male, first presented to Respondent for a physical evaluation.

Respondent's records indicate that Patient AM had no complaints except for weakness and generalized aches.

46. On January 6, 2003, Respondent's medical records for Patient AM indicate that he had a platelet count of 253,000.

47. Beginning on January 22, 2003, and continuing through October 29, 2003, Respondent prescribed and administered WinRh$_o$ infusion therapy to Patient A.M. at least 123 times. The treatments were generally administered twice a week.

48. On or about April 11, 2003, a blood test indicated that Patient AM's platelet count was 155,000.

49. On or about August 8, 2003, a blood test indicated that Patient AM's platelet count was 119,000.

50. On or about November 10, 2003, a blood test indicated that Patient AM's platelet count was 189,000.

51. Respondent's medical records for Patient AM indicate that he initiated the administration of infusion therapy when the patient's platelet count and condition did not warrant the therapy and continued the therapy without

adequate assessment of platelet counts, red cell counts, hemoglobin, reticulocyte levels, or the general efficacy of the continuation of the therapy.

52. Respondent's medical records for Patient AM's do not support a diagnosis of primary thrombocytopenia or ITP. Patient AM's thrombocytopenia was secondary to HIV.

53. At no time did Patient AM exhibit any of the conditions indicated as appropriate for repeated intravenous infusion of WinRh$_o$. Patient AM did not exhibit any active bleeding and there was no impending surgery.

54. Respondent did not adequately monitor Patient AM following WinRh$_o$ infusion therapy for known complications such as signs and/or symptoms of intravascular hemolysis (IVH), clinically compromising anemia, and renal insufficiency.

Patient JV

55. On July 9, 2003, Patient JV, an HIV positive male, first presented to Respondent for a physical evaluation. Patient JV reported a history of bleeding gums and bleeding disorders on his medical intake form, but Respondent's records do not indicate any active bleeding.

56. On or about July 9, 2003, Respondent ordered extensive laboratory tests for Patient JV. The blood test indicated JV's platelet count was 119,000.

57. Beginning on July 11, 2003, and continuing through November 14, 2003, Respondent prescribed and administered WinRh$_o$ infusion therapy to Patient JV 52 times. The treatments were generally administered twice a week.

58. On or about June 4, 2003, a blood test indicated that Patient JV's platelet count was 80,000

59. On or about September 2, 2003, blood test indicated that Patient JV's platelet count was 122,000.

60. On or about November 7, 2003, blood test indicated that Patient JV's platelet count was 95,000.

61. Respondent's medical records for Patient JV indicate that he initiated the administration of infusion therapy when the patient's platelet count and condition did not warrant the therapy and continued the therapy without adequate assessment of platelet counts, red cell counts, hemoglobin, reticulocyte levels, or the general efficacy of the continuation of the therapy.

62. Respondent's medical records for Patient JV do not support a diagnosis of primary thrombocytopenia or ITP. Patient JV's thrombocytopenia was secondary to HIV.

63. At no time did Patient JV exhibit any of the conditions indicated as appropriate for repeated intravenous infusion of $WinRh_o$. Patient JV did not exhibit any active bleeding and there was no impending surgery.

64. Respondent did not adequately monitor Patient JV following $WinRh_o$ infusion therapy for known complications such as signs and/or symptoms of intravascular hemolysis (IVH), clinically compromising anemia, and renal insufficiency.

65. Respondent continued to administer the $WinRh_o$ SDF treatment to Patient JV even though his platelet counts did not improve.

Patient RP

66. On February 28, 2003, Patient RP, an HIV positive male, presented to Respondent for a physical evaluation. Blood tests conducted during his initial visit indicated a normal platelet count.

67. Beginning on or about March 3, 2003, and continuing through August 11, 2003, Respondent prescribed and administered WinRh$_o$ infusion therapy to Patient RP 68 times. The treatments were generally administered twice a week.

68. Respondent's medical records for Patient RP indicate that he initiated the administration of infusion therapy when the patient's platelet count and condition did not warrant the therapy and continued the therapy without adequate assessment of platelet counts, red cell counts, hemoglobin, reticulocyte levels, or the general efficacy of the continuation of the therapy.

69. Respondent's medical records for Patient RP do not support a diagnosis of primary thrombocytopenia or ITP. Patient RP's thrombocytopenia was secondary to HIV.

70. At no time did Patient RP exhibit any of the conditions indicated as appropriate for repeated intravenous infusion of WinRh$_o$. Patient RP did not exhibit any active bleeding and there was no impending surgery.

71. Respondent did not adequately monitor Patient RP following WinRh$_o$ infusion therapy for known complications such as signs and/or symptoms of intravascular hemolysis (IVH), clinically compromising anemia, and renal insufficiency.

Patient ES

72. On or about April 2, 2003, Patient ES, an HIV positive male, first presented to Respondent for a physical evaluation. Patient ES reported on his medical history that he had a history of anemia. Respondent's medical records for Patient ES indicate that he presented with no complaints.

73. On or about April 2, 2003, Respondent ordered extensive laboratory tests on Patient ES. The blood test indicated Patient ES's platelet count was 181,000.

74. Beginning on or about April 25, 2003, and continuing through July 14, 2003 Respondent prescribed and administered WinRh$_o$ therapy to Patient ES 21 times. The treatments were generally administered twice a week.

75. Respondent's medical records for Patient ES indicate that he initiated the administration of infusion therapy when the patient's platelet count and condition did not warrant the therapy and continued the therapy without adequate assessment of platelet counts, red cell counts, hemoglobin, reticulocyte levels, or the general efficacy of the continuation of the therapy.

76. Respondent's medical records for Patient ES do not support a diagnosis of primary thrombocytopenia or ITP. Patient ES's thrombocytopenia was secondary to HIV.

77. At no time did Patient ES exhibit any of the conditions indicated as appropriate for repeated intravenous infusion of WinRh$_o$. Patient ES did not exhibit any active bleeding and there was no impending surgery.

78. Respondent did not adequately monitor Patient ES following WinRh$_o$ infusion therapy for known complications such as signs and/or symptoms of intravascular hemolysis (IVH), clinically compromising anemia, and renal insufficiency.

Patient AS

79. On or about May 5, 2003, Patient AS, an HIV positive male, presented to Respondent for a physical evaluation. Patient AS also presented with Hepatitis. Patient AS presented with no complaints of active bleeding or impending surgery.

80. On or about May 5, 2003, Respondent ordered extensive laboratory tests on Patient AS. The blood test indicated that Patient AS's platelet count was 137,000. Although the laboratory tests indicated an increased viral load,

Respondent's records did not document any assessment or treatment regarding Patient AS's viral load.

81. Beginning on May 7, 2003, and continuing through November 14, 2003, Respondent prescribed and administered WinRh$_o$ to Patient AS for a total of 82 treatments. The treatments were administered generally twice a week.

82. Respondent's medical records for Patient AS indicate that he initiated the administration of infusion therapy when the patient's platelet count and condition did not warrant the therapy and continued the therapy without adequate assessment of platelet counts, red cell counts, hemoglobin, reticulocyte levels, or the general efficacy of the continuation of the therapy.

83. Respondent's medical records for Patient AS do not support a diagnosis of primary thrombocytopenia or ITP. Patient AS's thrombocytopenia was secondary to HIV.

84. At no time did Patient AS exhibit any of the conditions indicated as appropriate for repeated intravenous infusion of WinRh$_o$. Patient AS did not exhibit any active bleeding and there was no impending surgery.

85. Respondent did not adequately monitor Patient AS following WinRh$_o$ infusion therapy for known complications such as signs and/or symptoms of

intravascular hemolysis (IVH), clinically compromising anemia, and renal insufficiency.

Patient AF1

86. On or about August 8, 2003, Patient AF1, a male previously diagnosed with Hepatitis C, presented to Respondent for a physical evaluation. Patient AF1 reported a history of nosebleeds and bleedings gums on his medical intake form but did not report any active bleeding or impending surgery.

87. On or about August 8, 2003, Respondent ordered extensive laboratory tests on Patient AF1 and the blood test indicated that Patient AF1's platelet count was 58,000.

88. Beginning on August 8, 2003, and continuing through November 14, 2003, Respondent prescribed and administered WinRh$_o$ to Patient AF1 for a total of 42 treatments. The treatments were administered generally twice a week.

89. Respondent's medical records for Patient AF1 indicate that he initiated the administration of infusion therapy when the patient's platelet count and condition did not warrant the therapy and continued the therapy without adequate assessment of platelet counts, red cell counts, hemoglobin, reticulocyte levels, or the general efficacy of the continuation of the therapy.

90. Respondent's medical records for Patient AF1 do not support a diagnosis of primary thrombocytopenia or ITP. Patient AF1's thrombocytopenia was secondary to HIV.

91. At no time did Patient AF1 exhibit any of the conditions indicated as appropriate for repeated intravenous infusion of WinRh$_o$. Patient AF1 did not exhibit any active bleeding and there was no impending surgery.

92. Respondent did not adequately monitor Patient AF1 following WinRh$_o$ infusion therapy for known complications such as signs and/or symptoms of intravascular hemolysis (IVH), clinically compromising anemia, and renal insufficiency.

Patient AF2

93. On May 26, 2003, Patient AF2, an HIV positive male, presented to Respondent for a physical evaluation. Respondent's medical records do not document any complaints from Patient AFS.

94. On May 26, 2003, Respondent ordered extensive laboratory tests on Patient AF2 and the blood test indicated that Patient AF2's platelet count was 90,000.

95. Beginning on June 2, 2003, and continuing through November 14, 2003, Respondent prescribed and administered WinRh$_o$ to Patient AF2 for a total of 77 treatments. The treatments were administered generally twice a week.

96. Respondent's medical records for Patient AF2 indicate that he initiated the administration of infusion therapy when the patient's platelet count and condition did not warrant the therapy and continued the therapy without adequate assessment of platelet counts, red cell counts, hemoglobin, reticulocyte levels, or the general efficacy of the continuation of the therapy.

97. Respondent's medical records for Patient AF2 do not support a diagnosis of primary thrombocytopenia or ITP. Patient AF2's thrombocytopenia was secondary to HIV.

98. At no time did Patient AF2 exhibit any of the conditions indicated as appropriate for repeated intravenous infusion of WinRh$_o$. Patient AF2 did not exhibit any active bleeding and there was no impending surgery.

99. Respondent did not adequately monitor Patient AF2 following WinRh$_o$ infusion therapy for known complications such as signs and/or symptoms of intravascular hemolysis (IVH), clinically compromising anemia, and renal insufficiency.

Patient CW

100. On or about May 22, 2002, Patient CW, an HIV positive male, presented to Respondent for a physical evaluation. Respondent's medical records indicate that Patient CW presented with no complaint of active bleeding or impending surgery.

101. On or about May 22, 2002, Respondent ordered extensive laboratory tests and the blood tests indicated that Patient CW's platelet count was 133,000.

102. On or about May 29, 2002, and continuing through November 7, 2003, Respondent prescribed and administered WinRh$_o$ to Patient AF2 for a total of 164 treatments. The treatments were administered generally twice a week.

103. On or about August 28, 2002, a blood test indicated Patient CW's platelet count was 107,000.

104. On or about December 2, 2002, a blood test indicated Patient CW had a platelet count of 135,000.

105. On or about March 3, 2003, a blood test indicated Patient CW had a platelet count of 315,000.

106. On or about June 18, 2003, a blood test indicated Patient CW had a platelet count of 237,000.

107. On or about August 27, 2003, a blood test indicated Patient CW had a platelet count of 119,000.

108. On September 12, 2003, a blood test indicated Patient CW had a platelet count of 246,000.

109. On or about November 7, 2003, a blood test indicated Patient CW had a platelet count of 313,000.

110. Respondent's medical records for Patient CW indicate that he initiated the administration of infusion therapy when the patient's platelet count and condition did not warrant the therapy and continued the therapy without adequate assessment of platelet counts, red cell counts, hemoglobin, reticulocyte levels, or the general efficacy of the continuation of the therapy.

111. Respondent's medical records for Patient CW do not support a diagnosis of primary thrombocytopenia or ITP. Patient CW's thrombocytopenia was secondary to HIV.

112. At no time did Patient CW exhibit any of the conditions indicated as appropriate for repeated intravenous infusion of WinRh$_o$. Patient CW did not exhibit any active bleeding and there was no impending surgery.

113. Respondent did not adequately monitor Patient CW following WinRh$_o$ infusion therapy for known complications such as signs and/or symptoms of intravascular hemolysis (IVH), clinically compromising anemia, and renal insufficiency.

Patient RS

114. On or about May 5, 2003, Patient RS, an HIV positive male with Hepatitis C, presented to Respondent for a physical evaluation. Respondent's medical records for Patient RS do not document any active bleeding or impending surgery.

115. On or about May 5, 2003, Respondent ordered extensive laboratory tests. The blood tests indicated that Patient RS's platelet count was 174,000.

116. On or about May 7, 2003, and continuing through October 22, 2003, Respondent prescribed and administered WinRh$_o$ to Patient RS for a total of 61 treatments. The treatments were administered generally twice a week.

117. On or about September 22, 2003, a blood test indicated that Patient RS had a platelet count of 166,000.

118. Respondent's medical records for Patient RS indicate that he initiated the administration of infusion therapy when the patient's platelet count and

condition did not warrant the therapy and continued the therapy without adequate assessment of platelet counts, red cell counts, hemoglobin, reticulocyte levels, or the general efficacy of the continuation of the therapy.

119. Respondent's medical records for Patient RS do not support a diagnosis of primary thrombocytopenia or ITP. Patient RS's thrombocytopenia was secondary to HIV.

120. At no time did Patient RS exhibit any of the conditions indicated as appropriate for repeated intravenous infusion of WinRh$_o$. Patient RS did not exhibit any active bleeding and there was no impending surgery.

121. Respondent did not adequately monitor Patient RS following WinRh$_o$ infusion therapy for known complications such as signs and/or symptoms of intravascular hemolysis (IVH), clinically compromising anemia, and renal insufficiency.

Patient MP

122. On or about April 4, 2003, Patient MP, an HIV positive male, presented to Respondent for a physical evaluation. Respondent's medical records for Patient MP do not document that Patient MP had any active bleeding or impending surgery.

123. On or about April 4, 2003, Respondent ordered extensive laboratory tests. The blood tests indicated that Patient MP's platelet count was 166,000.

124. On or about April 7, 2003, and continuing through November 3, 2003, Respondent prescribed and administered WinRh$_0$ to Patient MP for a total of 84 treatments. The treatments were administered generally twice a week.

125. On or about July 25, 2003, a blood test indicated that Patient MP had a platelet count of 158,000.

126. On or about October 29, 2003, a blood test indicated that Patient MP had a platelet count of 161,000.

127. Respondent's medical records for Patient MP indicate that he initiated the administration of infusion therapy when the patient's platelet count and condition did not warrant the therapy and continued the therapy without adequate assessment of platelet counts, red cell counts, hemoglobin, reticulocyte levels, or the general efficacy of the continuation of the therapy.

128. Respondent's medical records for Patient MP do not support a diagnosis of primary thrombocytopenia or ITP. Patient MP's thrombocytopenia was secondary to HIV.

129. At no time did Patient MP exhibit any of the conditions indicated as appropriate for repeated intravenous infusion of WinRh$_o$. Patient MP did not exhibit any active bleeding and there was no impending surgery.

130. Respondent did not adequately monitor Patient MP following WinRh$_o$ infusion therapy for known complications such as signs and/or symptoms of intravascular hemolysis (IVH), clinically compromising anemia, and renal insufficiency.

Patient SR

131. On or about April 23, 2003, Patient SR, an HIV positive male, presented to Respondent for a physical evaluation. Respondent's medical records for Patient SR do not document any active bleeding or impending surgery.

132. On or about April 23, 2005, Respondent ordered extensive laboratory tests. The blood tests indicated that Patient SR's platelet count was 145,000.

133. On or about April 28, 2003, and continuing through October 31, 2003, Respondent prescribed and administered intravenously WinRh$_o$ to Patient SR for a total of 79 treatments. The treatments were administered generally twice a week.

134. On or about July 25, 2003, a blood test indicated that Patient SR had a platelet count of 149,000.

135. On or about October 29, 2003, a blood test indicated that Patient SR had a platelet count of 154,000.

136. Respondent's medical records for Patient SR indicate that he initiated the administration of infusion therapy when the patient's platelet count and condition did not warrant the therapy and continued the therapy without adequate assessment of platelet counts, red cell counts, hemoglobin, reticulocyte levels, or the general efficacy of the continuation of the therapy.

137. Respondent's medical records for Patient SR do not support a diagnosis of primary thrombocytopenia or ITP. Patient SR's thrombocytopenia was secondary to HIV.

138. At no time did Patient SR exhibit any of the conditions indicated as appropriate for repeated intravenous infusion of WinRh$_o$. Patient SR did not exhibit any active bleeding and there was no impending surgery.

139. Respondent did not adequately monitor Patient SR following WinRh$_o$ infusion therapy for known complications such as signs and/or symptoms of

intravascular hemolysis (IVH), clinically compromising anemia, and renal insufficiency.

Patient CH

140. On or about March 24, 2003, Patient CH, an HIV positive male, presented to Respondent for a physical evaluation. Respondent's medical records for Patient CH do not document any active bleeding or impending surgery.

141. On or about March 24, 2003 Respondent ordered extensive laboratory tests. The blood tests indicated that Patient CH's platelet count was 122,000.

142. Beginning on or about March 26, 2003, and continuing through September 28, 2003, Respondent prescribed and administered intravenous WinRh$_o$ to Patient CH for a total of 61 treatments. The treatments were administered approximately twice a week.

143. Although Respondent's records for Patient CH contain laboratory test results dated August 8, 2003, there are no results for CH's platelet counts.

144. Respondent's medical records for Patient CH indicate that he initiated the administration of infusion therapy when the patient's platelet count and

condition did not warrant the therapy and continued the therapy without adequate assessment of platelet counts, red cell counts, hemoglobin, reticulocyte levels, or the general efficacy of the continuation of the therapy.

145. Respondent's medical records for Patient CH do not support a diagnosis of primary thrombocytopenia or ITP. Patient SR's thrombocytopenia was secondary to HIV.

146. At no time did Patient CH exhibit any of the conditions indicated as appropriate for repeated intravenous infusion of $WinRh_o$. Patient CH did not exhibit any active bleeding and there was no impending surgery.

147. Respondent did not adequately monitor Patient CH following $WinRh_o$ infusion therapy for known complications such as signs and/or symptoms of intravascular hemolysis (IVH), clinically compromising anemia, and renal insufficiency.

COUNT ONE

~~148. Petitioner reallages paragraphs 1 through 147 and incorporates~~ them as if set out herein.

149. Section 458.331(1)(t), Florida Statutes (2001)(2002)(2003), ~~subjects a licensee to discipline for gross or repeated malpractice~~ or the failure to

practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances.

150. Respondent did not meet the applicable standard of care in his use of WinRh$_o$ treatments to the above patients in one or more of the following ways;

a. The prescribed treatment was not indicated for these patients; or,

b. The diagnosis of primary thrombocytopenia is not supported by the patient's medical records; or,

c. The follow-up laboratory tests were inadequate to determine the patients' response to the treatments; or

d. Respondent administered infusion therapy to the above-described patients at the same dosage repeatedly regardless of whether the platelet counts went up or down; or

e. Respondent failed to address significant abnormal test results, such as viral loads, while pursuing the inappropriate treatment for thrombocytopenia secondary to HIV or Hepatitis C; or

f. Respondent's medical records are grossly inadequate to document how the patients' serious medical conditions were being addressed other than through the ineffective WinRho therapy.

151. Based on the foregoing, Respondent violated Section 458.331(1)(t), Florida Statutes, by engaging in gross or repeated malpractice or by failing to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances.

COUNT TWO

152. Petitioner realleges and incorporates paragraphs 1 through 147 as if fully set forth herein.

153. Section 458.331(1)(m), Florida Statutes (2001)(2002)(2003), subjects a licensee to discipline for failing to keep legible, as defined by department rule in consultation with the board, medical records that justify the course of treatment of patients, including, but not limited to, patient histories, examination results, test results, or treatment plans.

154. Respondent's medical records for the above-described patients do not justify the course of repeated WinRh$_0$ infusion treatments in that the records do not include documentation regarding the adequate monitoring of patients following treatment, any follow-up examination results, blood test results, or alternative treatment plans.

155. Based on the foregoing, Respondent has violated Section 458.331(1)(m), Florida Statutes (2001)(2002)(2003), by failing to keep legible, as defined by department rule in consultation with the board, medical records that justify the course of treatment of patients, including, but not limited to, patient histories, examination results, test results, or treatment plans.

WHEREFORE, the Petitioner respectfully requests that the Board of Medicine enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems

appropriate.

SIGNED this _____ day of November 13, **_____, 2006.**

M. Rony François, M.D., M.S.P.H., Ph.D.
Secretary, Department of Health

FILED
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PCP: May 28, 2006
PCP Members: El-Bahri, Coto, Dyches