COMMONWEALTH OF KENTUCKY
BOARD OF MEDICAL LICENSURE
CASE NO. 2067

IN RE: THE LICENSE TO PRACTICE MEDICINE IN THE COMMONWEALTH OF KENTUCKY HELD BY JAMES M. FOSTER, M.D., LICENSE NO. 32681, 275 SOUTH LIMESTONE, SUITE 150, LEXINGTON, KENTUCKY 40508

AMENDED AGREED ORDER

Come now the Kentucky Board of Medical Licensure (hereafter "the Board"), acting by and through its Inquiry Panel A, and JAMES M. FOSTER, M.D., (hereafter "the licensee"), and, based upon their mutual desire to fully and finally resolve this pending investigation without an evidentiary hearing, hereby ENTER INTO the following **AMENDED AGREED ORDER**:

STIPULATIONS OF FACT

The parties stipulate the following facts, which serve as the factual bases for this Amended Agreed Order:

1. At all relevant times, James M. Foster, M.D., was licensed by the Board to practice medicine within the Commonwealth of Kentucky.
2. The licensee's medical specialty is General Medicine.
3. The Board opened an investigation pursuant to a grievance received on or about April 19, 2021 from an investigator with the Special Investigations Unit of Humana Insurance. The grievance expressed concern with the licensee's prescribing of Testosterone and Anastrolze.
4. In an interview with a Board investigator, the licensee stated that he prescribes testosterone for middle-aged men with low testosterone as a part of Testosterone Replacement Therapy. The licensee stated that this can cause estrogen to go up in

males and therefore he prescribes the drug Anastrozole to counter the effects of the estrogen. The licensee stated that while such use was off-label, it was standard practice.

5. The licensee responded to the grievance in writing on July 2, 2021, and again through his counsel on August 17, 2021.

6. The Board obtained twelve (12) medical charts of patients receiving Anastrozole and/or testosterone.

7. A Board consultant who is Board-certified in Endocrinology reviewed the licensee's twelve (12) patient charts and found that the licensee departed from or failed to conform to acceptable and prevailing medical practices in regard to diagnoses in ten (10) charts, in regard to treatment in ten (10) charts, overall in ten (10) charts and was overall Borderline in two (2) charts. The Board consultant also found instances of gross negligence and gross ignorance. The Board consultant's report is attached to the Agreed Order filed of record September 2, 2022 and is incorporated in its entirety.

8. On or about April 19, 2022, the licensee responded in writing, through counsel, to the Board consultant's review of his patient charts. In his response, the licensee responded to the Board consultant's concerns and included a letter of support from Ashok Kadambi, M.D., a physician who practices hormone optimization in Ft. Wayne, Indiana. The licensee explained that he was completing a mentoring program with Dr. Kadambi. The licensee submitted an additional response, through counsel, on April 25, 2022.

9. On or about June 28, 2022, the Board consultant issued a final report after reviewing the licensee's responses. The Board consultant responded to the comments made by the licensee and Dr. Kadambi. The Board consultant's opinion from her initial review did not change.

10. On August 18, 2022, the Board's Inquiry Panel A reviewed the investigation. The licensee appeared, with counsel, and addressed the Panel. The Panel and the licensee agreed to enter into an Agreed Order, in lieu of the issuance of a Complaint and Emergency Order of Restriction.

11. The Agreed Order, filed of record on September 2, 2022, required that the licensee's Kentucky medical license SHALL BE SUBJECT TO THE FOLLOWING TERMS AND CONDITIONS OF RESTRICTION/LIMITATION until further order of the Board:

    a. The licensee SHALL NOT practice medicine in the context of hormone replacement and/or optimization therapy until further order of the Panel;

    b. Within twenty (20) days of the filing of this Agreed Order, the licensee SHALL contact *either* the Center for Personalized Education for Physicians ("CPEP"), 720 South Colorado Boulevard, Suite 1100-N, Denver, Colorado 80246, Tel. (303) 577-3232 *or* LifeGuard, 400 Winding Creek Boulevard, Mechanicsburg, Pennsylvania, 17050, Tel. (717) 909-2590, to schedule a clinical skills assessment in hormone replacement and/or optimization therapy, for the earliest dates available to both CPEP/LifeGuard and the licensee;

        i. Both parties may provide relevant information to CPEP/LifeGuard for consideration as part of the clinical skills assessment. In order to permit the Board to provide such relevant information, the licensee SHALL immediately notify the Board's Legal Department of the assessment dates once the assessment is scheduled;

        ii. The licensee SHALL travel to CPEP/LifeGuard and complete the assessment as scheduled, at his expense;

iii. The licensee expressly understands and agrees that CPEP/LifeGuard will issue its final assessment report, in accordance with its internal policies;

iv. The licensee SHALL take all steps necessary, including signing any waiver and/or consent forms required to ensure that CPEP/LifeGuard will provide a copy of the assessment report to the Board's Legal Department promptly after its completion;

v. If the assessment report recommends development of an educational plan or a remediation plan, the licensee SHALL take all necessary steps to arrange for CPEP/Lifeguard to immediately develop such a plan and enter into any necessary oversight monitoring agreement with CPEP/LifeGuard, at the licensee's expense, so that the proposed educational plan or remediation plan may be presented to the Panel for review along with the assessment report;

vi. The licensee expressly understands and agrees that if the CPEP/LifeGuard assessment report recommends that the licensee retrain in a residency or residency-like setting, the licensee SHALL NOT perform any act which would constitute the "practice of medicine or osteopathy," as that term is defined in KRS 311.550(10) – the diagnosis, treatment, or correction of any and all human conditions, ailments, diseases, injuries, or infirmities by any and all means, methods, devices, or instrumentalities – in the Commonwealth of Kentucky, unless and until approved to do so by the Panel;

c. Pursuant to KRS 311.565(1)(v), the licensee SHALL REIMBURSE to the Board the costs of the investigation in the amount of $7,787.50 within one (1) year from entry of this Agreed Order; and

d. The licensee SHALL NOT violate any provision of KRS 311.595 and/or 311.597.

12. The licensee obtained a clinical skills assessment in hormone replacement/optimization therapy through the Center for Personalized Education for Professionals ("CPEP") in December 2022. CPEP issued an Assessment Report on April 3, 2023. The results of the assessment identified concerns, stating in sum:

> Based on Dr. Foster's performance during this Assessment and the extent of educational needs identified, CPEP opines that Dr. Foster's performance in the area of hormone replacement/optimization is consistent with finding (c) [not safe to practice independently at this time], which involves remediating in a setting that can provide supervision, such as a residency, fellowship, or similar setting.

13. In or around April 2023, this Amended Agreed Order was entered into because the licensee agreed that if CPEP recommended that he "retrain in a residency or residency-like setting," the licensee shall not perform any act which would constitute the "practice of medicine or osteopathy," as that term is defined in KRS 311.550(10).

STIPULATED CONCLUSIONS OF LAW

The parties stipulate the following Conclusions of Law, which serve as the legal bases for this Amended Agreed Order:

1. The licensee's Kentucky medical license is subject to regulation and discipline by the Board.
2. Based upon the Stipulations of Fact, the licensee has engaged in conduct which violates the provisions of KRS 311.595(9), as illustrated by KRS 311.597(3) and (4). Accordingly, there are legal grounds for the parties to enter into this Amended Agreed Order.
3. Pursuant to KRS 311.591(6) and 201 KAR 9:082, the parties may fully and finally resolve this pending investigation without an evidentiary hearing by entering into an informal resolution such as this Amended Agreed Order.

AMENDED AGREED ORDER

Based upon the foregoing Stipulations of Fact and Stipulated Conclusions of Law, and, based upon their mutual desire to fully and finally resolve this pending investigation

without an evidentiary hearing, the parties hereby ENTER INTO the following **AMENDED AGREED ORDER:**

1. The license to practice medicine in the Commonwealth of Kentucky held by JAMES M. FOSTER, M.D., is RESTRICTED/LIMITED FOR AN INDEFINITE PERIOD OF TIME, effective immediately upon the filing of this Amended Agreed Order;

2. During the effective period of this Amended Agreed Order, the licensee's Kentucky medical license SHALL BE SUBJECT TO THE FOLLOWING TERMS AND CONDITIONS until further order of the Board:

    a. The licensee SHALL NOT perform any act which would constitute the "practice of medicine or osteopathy," as that term is defined in KRS 311.550(10) – the diagnosis, treatment, or correction of any and all human conditions, ailments, diseases, injuries, or infirmities by any and all means, methods, devices, or instrumentalities – in the Commonwealth of Kentucky, unless and until approved to do so by the Panel;

    b. Pursuant to KRS 311.565(1)(v), the licensee SHALL REIMBURSE to the Board the costs of the investigation in the amount of $7,787.50 on or before September 2, 2023; and

    c. The licensee SHALL NOT violate any provision of KRS 311.595 and/or 311.597.

3. The licensee expressly understands and agrees that the Panel will not consider a request to amend or terminate this Amended Agreed Order unless and until the licensee has retrained in a residency or fellowship setting in an ABMS-recognized specialty of endocrinology, obstetrics/gynecology or urology which include components specific to hormone replacement.

4. The licensee expressly agrees that if he should violate any term or condition of this Amended Agreed Order, the licensee's practice shall constitute an immediate danger to the public health, safety, or welfare, as provided in KRS 311.592 and

13B.125. The parties further agree that if the Board should receive information that he has violated any term or condition of this Amended Agreed Order, the Panel Chair is authorized by law to enter an Emergency Order of Suspension or Restriction immediately upon a finding of probable cause that a violation has occurred, after an *ex parte* presentation of the relevant facts by the Board's General Counsel or Assistant General Counsel. If the Panel Chair should issue such an Emergency Order, the parties agree and stipulate that a violation of any term or condition of this Amended Agreed Order would render the licensee's practice an immediate danger to the health, welfare and safety of patients and the general public, pursuant to KRS 311.592 and 13B.125; accordingly, the only relevant question for any emergency hearing conducted pursuant to KRS 13B.125 would be whether the licensee violated a term or condition of this Amended Agreed Order.

5. The licensee understands and agrees that any violation of the terms of this Amended Agreed Order would provide a legal basis for additional disciplinary action, including revocation, pursuant to KRS 311.595(13).

SO AGREED on this 20th day of April, 2023.

FOR THE LICENSEE:

JAMES M. FOSTER, M.D.

LISA ENGLISH HINKLE
COUNSEL FOR THE LICENSEE

FOR THE BOARD:

WAQAR A. SALEEM, M.D.
CHAIR, INQUIRY PANEL A

NICOLE A. KING
Assistant General Counsel
Kentucky Board of Medical Licensure
310 Whittington Parkway, Suite 1B
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(502) 429-7150

COMMONWEALTH OF KENTUCKY
BOARD OF MEDICAL LICENSURE
CASE NO. 2067

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AGREED ORDER

Come now the Kentucky Board of Medical Licensure (hereafter "the Board"), acting by and through its Inquiry Panel A, and JAMES M. FOSTER, M.D., (hereafter "the licensee"), and, based upon their mutual desire to fully and finally resolve this pending investigation without an evidentiary hearing, hereby ENTER INTO the following **AGREED ORDER**:

STIPULATIONS OF FACT

The parties stipulate the following facts, which serve as the factual bases for this Agreed Order:

1. At all relevant times, James M. Foster, M.D., was licensed by the Board to practice medicine within the Commonwealth of Kentucky.
2. The licensee's medical specialty is General Medicine.
3. The Board opened an investigation pursuant to a grievance received on or about April 19, 2021 from an investigator with the Special Investigations Unit of Humana Insurance. The grievance expressed concern with the licensee's prescribing of Testosterone and Anastrolze.
4. In an interview with a Board investigator, the licensee stated that he prescribes testosterone for middle-aged men with low testosterone as a part of Testosterone Replacement Therapy. The licensee stated that this can cause estrogen to go up in

males and therefore he prescribes the drug Anastrozole to counter the effects of the estrogen. The licensee stated that while such use was off-label, it was standard practice.

5. The licensee responded to the grievance in writing on July 2, 2021, and again through his counsel on August 17, 2021.
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7. A Board consultant who is Board-certified in Endocrinology reviewed the licensee's twelve (12) patient charts and found that the licensee departed from or failed to conform to acceptable and prevailing medical practices in regard to diagnoses in ten (10) charts, in regard to treatment in ten (10) charts, overall in ten (10) charts and was overall Borderline in two (2) charts. The Board consultant also found instances of gross negligence and gross ignorance. The Board consultant's report is attached and incorporated in its entirety.
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comments made by the licensee and Dr. Kadambi. The Board consultant's opinion from her initial review did not change.

10. On August 18, 2022, the Board's Inquiry Panel A reviewed the investigation. The licensee appeared, with counsel, and addressed the Panel. The Panel and the licensee agree to enter into this Agreed Order, in lieu of the issuance of a Complaint and Emergency Order of Restriction.

STIPULATED CONCLUSIONS OF LAW

The parties stipulate the following Conclusions of Law, which serve as the legal bases for this Agreed Order:

1. The licensee's Kentucky medical license is subject to regulation and discipline by the Board.
2. Based upon the Stipulations of Fact, the licensee has engaged in conduct which violates the provisions of KRS 311.595(9), as illustrated by KRS 311.597(3) and (4). Accordingly, there are legal grounds for the parties to enter into this Agreed Order.
3. Pursuant to KRS 311.591(6) and 201 KAR 9:082, the parties may fully and finally resolve this pending investigation without an evidentiary hearing by entering into an informal resolution such as this Agreed Order.

AGREED ORDER

Based upon the foregoing Stipulations of Fact and Stipulated Conclusions of Law, and, based upon their mutual desire to fully and finally resolve this pending investigation without an evidentiary hearing, the parties hereby ENTER INTO the following **AGREED ORDER:**

1. The license to practice medicine in the Commonwealth of Kentucky held by JAMES M. FOSTER, M.D., is RESTRICTED/LIMITED FOR AN INDEFINITE PERIOD OF TIME, effective immediately upon the filing of this Order;

2. During the effective period of this Agreed Order, the licensee's Kentucky medical license SHALL BE SUBJECT TO THE FOLLOWING TERMS AND CONDITIONS OF RESTRICTION/LIMITATION until further order of the Board:

    a. The licensee SHALL NOT practice medicine in the context of hormone replacement and/or optimization therapy until further order of the Panel;

    b. Within twenty (20) days of the filing of this Agreed Order, the licensee SHALL contact *either* the Center for Personalized Education for Physicians ("CPEP"), 720 South Colorado Boulevard, Suite 1100-N, Denver, Colorado 80246, Tel. (303) 577-3232 *or* LifeGuard, 400 Winding Creek Boulevard, Mechanicsburg, Pennsylvania, 17050, Tel. (717) 909-2590, to schedule a clinical skills assessment in hormone replacement and/or optimization therapy, for the earliest dates available to both CPEP/LifeGuard and the licensee;

        i. Both parties may provide relevant information to CPEP/LifeGuard for consideration as part of the clinical skills assessment. In order to permit the Board to provide such relevant information, the licensee SHALL immediately notify the Board's Legal Department of the assessment dates once the assessment is scheduled;

        ii. The licensee SHALL travel to CPEP/LifeGuard and complete the assessment as scheduled, at his expense;

        iii. The licensee expressly understands and agrees that CPEP/LifeGuard will issue its final assessment report, in accordance with its internal policies;

        iv. The licensee SHALL take all steps necessary, including signing any waiver and/or consent forms required to ensure that CPEP/LifeGuard will provide a copy of the assessment report to the Board's Legal Department promptly after its completion;

        v. If the assessment report recommends development of an educational plan or a remediation plan, the licensee SHALL take

all necessary steps to arrange for CPEP/Lifeguard to immediately develop such a plan and enter into any necessary oversight monitoring agreement with CPEP/LifeGuard, at the licensee's expense, so that the proposed educational plan or remediation plan may be presented to the Panel for review along with the assessment report;

vi. The licensee expressly understands and agrees that if the CPEP/LifeGuard assessment report recommends that the licensee retrain in a residency or residency-like setting, the licensee SHALL NOT perform any act which would constitute the "practice of medicine or osteopathy," as that term is defined in KRS 311.550(10) – the diagnosis, treatment, or correction of any and all human conditions, ailments, diseases, injuries, or infirmities by any and all means, methods, devices, or instrumentalities – in the Commonwealth of Kentucky, unless and until approved to do so by the Panel;

c. Pursuant to KRS 311.565(1)(v), the licensee SHALL REIMBURSE to the Board the costs of the investigation in the amount of $7,787.50 within one (1) year from entry of this Agreed Order; and

d. The licensee SHALL NOT violate any provision of KRS 311.595 and/or 311.597.

3. The licensee expressly understands and agrees that the Panel will not consider a request to amend or terminate this Agreed Order unless and until the Panel has received the final assessment report and education/remediation plan (if recommended) from CPEP/LifeGuard for review.

4. The licensee expressly understands and agrees that if the Panel should grant the licensee's request to reinstate the full practice of medicine in the future, it will do so by an Amended Agreed Order, which shall at least require that:

a. The licensee successfully complete the CPEP/LifeGuard education/remediation plan, if such a plan is recommended and developed, at his expense and as directed by CPEP/LifeGuard; and

b. Any other conditions deemed necessary by the Panel at that time.

5. The licensee expressly agrees that if he should violate any term or condition of this Agreed Order, the licensee's practice shall constitute an immediate danger to the public health, safety, or welfare, as provided in KRS 311.592 and 13B.125. The parties further agree that if the Board should receive information that he has violated any term or condition of this Agreed Order, the Panel Chair is authorized by law to enter an Emergency Order of Suspension or Restriction immediately upon a finding of probable cause that a violation has occurred, after an *ex parte* presentation of the relevant facts by the Board's General Counsel or Assistant General Counsel. If the Panel Chair should issue such an Emergency Order, the parties agree and stipulate that a violation of any term or condition of this Agreed Order would render the licensee's practice an immediate danger to the health, welfare and safety of patients and the general public, pursuant to KRS 311.592 and 13B.125; accordingly, the only relevant question for any emergency hearing conducted pursuant to KRS 13B.125 would be whether the licensee violated a term or condition of this Agreed Order.

6. The licensee understands and agrees that any violation of the terms of this Agreed Order would provide a legal basis for additional disciplinary action, including revocation, pursuant to KRS 311.595(13).

SO AGREED on this 31st day of August, 2022.

FOR THE LICENSEE:

JAMES M. FOSTER, M.D.

LISA ENGLISH HINKLE
COUNSEL FOR THE LICENSEE

FOR THE BOARD: W. Saleem.

WAQAR A. SALEEM, M.D.
CHAIR, INQUIRY PANEL A

Sara Farmer

SARA FARMER
Assistant General Counsel
Kentucky Board of Medical Licensure
310 Whittington Parkway, Suite 1B
Louisville, Kentucky 40222
(502) 429-7150

KENTUCKY BOARD OF MEDICAL LICENSURE

EXPERT REVIEW WORKSHEET

(Please type)

Case No.__ Patient Name[redacted]
Expert's Name__Sathya Krishnasamy_____

1. Brief description of symptom, dx and course of treatment: _____

30 y male with history of recovering alcoholism, stress, pandemic related issues
And non-specific symptoms.
BP 137/99
HR 79/m
BMI 28.89 (30 kg/m2 by bodpod)

Levels drawn at 1pm afternoon on 6.8.2020
Value not repeated before starting treatment (preferable am if patient not 3rd shift)
Also, at initial physical exam, no genitalia evaluation for primary testicular failure.
Patient had abnormal thyroid function, elevated ALT levels
And multiple nonspecific symptoms.
Started on testosterone injections at 0.6 ml 2xweekly
Also, on anastrazole
Clomiphene citrate
HCG injections
IGF-1 LR3 inj
MK677 (GH secretogogues)

Repeat labs were drawn only after 8 months (March 2021)
Which showed high testosterone levels, high hemoglobin/hematocrit
Persistent thyroid function abnormality.
Phlebotomy recommended.
While documented to change of dose to 0.5 ml 2xweekly
Discrepancy with
He administered dose at 0.6 ml 2xweek with no lab follow up

No exam of thyroid
Weight not noted.

2. Can you form an opinion? Based on your background and experience and review of all information provided you, and assuming that the treatment as documented was provided, can you form an opinion as to whether the care rendered by the care

provider, including diagnosis, treatment or record keeping, departed from or failed to conform to the minimal standards of acceptable and prevailing medical practice (in the medical community at large)?

_____x__ Yes, I can form an opinion.

_____ No, I cannot form an opinion.

_____ I need more information (specify): _____

3. What is your opinion? Please use the definitions below as "guidelines" to be used in defining standard of practice. You are not limited to these guidelines in forming your opinion, but please state your own additional criteria if applicable.

   a. Diagnosis. Evaluation of a medical problem using means such as history, physical examination, laboratory, and radiographic studies, when applicable.

      ____x__ Below minimum standards

      _____ Within minimum standards

   b. Treatment. Use of medications and other modalities based on generally accepted and approved indications, with proper precautions to avoid adverse physical reactions, habituation or addiction.

      ___x___ Below minimum standards

      _____ Within minimum standards

   c. Records.

      Maintenance of records which should contain, at a minimum, the following: (1) appropriate history and physical and/or mental examination for the patient's chief complaint relevant to the physician's specialty; (2) results of diagnostic tests (when indicated); (3) a working diagnosis; (4) notes on treatment(s) undertaken; (5) a record by date of all prescriptions for drugs, with names of medications, strengths , dosages, quantity, and number of refills; and (6) a record of billings.

      _____ Below minimum standards

      ____x__ Within minimum standards

   d. Overall Opinion. Based on the foregoing, what is your overall opinion?

__x____ **Clearly below minimum standards.**

_____ **Clearly within minimum standards**

__ ___ **Borderline Case**

c. **Gross Ignorance, Gross Negligence, Gross Incompetence. If you found that this physician did not meet the minimum standards of care in treating a patient(s), did you also conclude that any of these departures from the minimum standards of care were so serious that you consider them to exhibit gross ignorance, gross negligence, and/or gross incompetence on the physician's part. If "yes," please identify each of these instances, classify it appropriately and explain your reasoning in reaching that conclusion(s). If "yes," please also indicate whether you found a pattern of gross ignorance, gross negligence and/or gross incompetence in this physician's practice as evidenced by the records reviewed and explain your conclusion(s).**

_____**Gross negligence**

4. **Explain your opinion. If you opined that practice was below minimum standard for any of the above reasons, state the correct minimal standard of practice (NOTE: It is not sufficient to say "I would have..., or I would have not...", you should be able to testify that "the minimal standard of practice in the medical community at large would be to...") Use extra sheets as necessary to explain your opinion and complete this report.**

The standard practice is to measure am sample of testosterone and repeat to confirm.

This 30 yr. young male patient has history of alcoholism but has been in recovery for 4 years (per history)
ALT elevated and worsened at follow up after testosterone was started.
Patient also had abnormal thyroid levels
No thyroid or testicular exam conducted.
While licensee repeated the thyroid levels 8 months later, no further evaluation or referral to internist was noted.
Was patient on biotin or iodine supplements?
Is he clinically hyperthyroid?

ALT was not further worked up given other differential diagnosis.
Given high Iron levels, transaminitis, and lower T levels, hemochromatosis is a possibility.
Sleep studies or diagnosis of OSA not documented given BMI before starting androgen.
I do not see any bone health evaluation given anastrozole was prescribed.
Also, it is mentioned that patient received injections 3 days prior to lab (3/12/21 and 3/15/21).
However, I don't see the visit documented after June 2020.
Until 3.15.21.
Also, patient complained of chest tenderness (likely gynecomastia) on anastrazole

IR was in 90s.
No further evaluation other than recommendation for phlebotomy.
Even if levels were justified by proximity to injections,
Standard of care would be to repeat labs and
, also given hemoglobin is elevated, would have decreased the dose.

 # MK677 and IGF-1 LR3 are oral and injectable GH secretagogues respectively.
The long-term safety has not been evaluated in trials for malignancy potential in human subjects.
Sheep fetus studies have shown islet defects, adrenal steroidogenesis defects and impact on intestinal and cardiomyocyte hypertrophy.
Has been banned in sports (doping by athletes for performance enhancing).
I am concerned about safety of prescribing these products at this time until human safety trials established, not to mention the cost to the patient.
IGF-1 levels were not monitored either.

1 · 17 · 2022 — **Date of Review**

Signature of Expert

date	lab	T dose	thyroid	comments
6.8.2020	TT-FT-BAT-		TSH 0.37 uiu/ml Free t4 3.1 ng dl	Alt 59u l

T-Shot

140pm	SHBG 351-26-57-60		No thyroid or testicular exam No repeat labs until march 2021	FSH 14 miu/ml Iron 197meg/dl IGF-1 100 ng/l
6.15.20		0.6 ml 2xweek Until 3/2021	**No evaluation until 9 months later.**	IGF-1 LR3. MK677 HCG Anastrazole Metformin Crestor Acarbose (?)
3.15.2021	TT-FT-BAT-SHBG (372-210-470-37 H/H 17.8/50.5	**0.5 ml** **2xweek** Advised phlebotomy	TSH 0.32 No free t4 HR 92/min No weight c/o chest tenderness	ALT 89 u/l With abnormal lfts no further testing done Such as evaluation for hemochromatosis, hepatitis (transaminitis panel)
5.21.2021		**Dose documented as 0.6 ml** **2x week** **No explanation for dose change**		**No lab** **last record 7/19/2021**

KENTUCKY BOARD OF MEDICAL LICENSURE

EXPERT REVIEW WORKSHEET

(Please type)

Case No._____ Patient Name [redacted]

Expert's Name___Sathya Krishnasamy____

1. **Brief description of symptom, dx and course of treatment:** _____

40 y old 3rd shift worker seen for fatigue, low energy
Testosterone total at 930am (quest MS) was 437 ng/dl. SHBG 44 nmol/L
FSH 10 miu/ml. LH 4.5 miu/ml
Exam: no genital exam given higher FSH
Was started on 100 mg testosterone bi-weekly,
anastrazole and finasteride
Along with multiple supplements
Metformin started although A1c 5.1% and glucose 95 mg/dl

2. **Can you form an opinion? Based on your background and experience and review of all information provided you, and assuming that the treatment as documented was provided, can you form an opinion as to whether the care rendered by the care provider, including diagnosis, treatment or record keeping, departed from or failed to conform to the minimal standards of acceptable and prevailing medical practice (in the medical community at large)?**

   _____x_ **Yes, I can form an opinion.**

   _____ **No, I cannot form an opinion.**

   _____ **I need more information (specify):** _____

3. **What is your opinion? Please use the definitions below as "guidelines" to be used in defining standard of practice. You are not limited to these guidelines in forming your opinion, but please state your own additional criteria if applicable.**

   a. **Diagnosis. Evaluation of a medical problem using means such as history, physical examination, laboratory, and radiographic studies, when applicable.**

      ___x___ **Below minimum standards**

      _____ **Within minimum standards**

b. **Treatment. Use of medications and other modalities based on generally accepted and approved indications, with proper precautions to avoid adverse physical reactions, habituation or addiction.**

_____x_ **Below minimum standards**

_____ **Within minimum standards**

c. **Records.**

Maintenance of records which should contain, at a minimum, the following: (1) appropriate history and physical and/or mental examination for the patient's chief complaint relevant to the physician's specialty; (2) results of diagnostic tests (when indicated); (3) a working diagnosis; (4) notes on treatment(s) undertaken; (5) a record by date of all prescriptions for drugs, with names of medications, strengths , dosages, quantity, and number of refills; and (6) a record of billings.

_____ **Below minimum standards**

__x____ **Within minimum standards**

d. **Overall Opinion. Based on the foregoing, what is your overall opinion?**

__x____ **Clearly below minimum standards.**

_____ **Clearly within minimum standards**

_____ **Borderline Case**

e. **Gross Ignorance, Gross Negligence, Gross Incompetence. If you found that this physician did not meet the minimum standards of care in treating a patient(s), did you also conclude that any of these departures from the minimum standards of care were so serious that you consider them to exhibit gross ignorance, gross negligence, and/or gross incompetence on the physician's part. If "yes," please identify each of these instances, classify it appropriately and explain your reasoning in reaching that conclusion(s). If "yes," please also indicate whether you found a pattern of gross ignorance, gross negligence and/or gross incompetence in this physician's practice as evidenced by the records reviewed and explain your conclusion(s).**

Gross negligence

did not meet minimum standards for treatment of hypogonadism
No clear indication for metformin

4. **Other questions from the Medical Board (ignore if blank):** _____

5. **Explain your opinion. If you opined that practice was below minimum standard for any of the above reasons, state the correct minimal standard of practice (NOTE: It is not sufficient to say "I would have..., or I would have not...", you should be able to testify that "the minimal standard of practice in the medical community at large would be to...") Use extra sheets as necessary to explain your opinion and complete this report.**

Patient is a 3rd shift worker
Testosterone levels at 9am in 3rd shift worker would be low (expected)
More over, levels need to be repeated before initiating testosterone replacement (Ref Endocrine society 2018)
There was no clear diagnosis
Symptoms of low testosterone is a very general term and nonspecific for starting such high doses of testosterone which may have harmful effects on patient.
In this patient there was also slightly elevated FSH, that was not pursued further with physical exam and repeat gonadotropins
No history of decreased body hair.
Prescribed Dose of testosterone was quite high, with supraphysiologic levels
Dose was not decreased after first treatment lab draw (11 2019)
Hematocrit was high
Blood donation is not approved treatment for testosterone induced erythrocytosis
Metformin prescribed for patient with no known prediabetes by A1c or fasting Blood glucose.
Several other supplements were recommended with no known benefit(cost).

1. 17. 22
Date of Review

Signature of Expert

KENTUCKY BOARD OF MEDICAL LICENSURE

EXPERT REVIEW WORKSHEET

(Please type)

Case No._2[redacted]_____ Patient Name__

Expert's Name__Suthya Krishnasamy___

1. Brief description of symptom, dx and course of treatment: _____

patient was followed by licensee for several years before available records, was treated for stress related to divorce, hectic work life (per narrative)
No clear medical diagnosis based on evaluation.
We don't have initial work up details.
At 12/2017, his Rx was filled without any lab data.
It was noted prescriptions includes oxycodone.
Unclear if it is opioid related hypogonadism.
However, it is not documented by licensee as above.
Also, cjc was recommended

Initial documented testosterone levels available were low at 229 ng (RIA quest) Jan 2019 however and it is not clear if he had been out of treatment recently which may show low levels while HPA axis recovers.
He was initiated on 300 mg testosterone weekly (1.5 cc)
The prescription was written as 7.7 cc weekly
I wonder if that was a typo.
E-script reflected that dose too.
However, his clinic injections were at 300 mg (1.5 ml) weekly.
He was also started on somatropin injections based on one IGF-1 value.
(No dynamic testing conducted)
His medical history includes dyslipidemia, obesity class 2, stress
And history of necrozing skin infection (records unavailable)
He has also been on steroids intermittently for various reasons
No sleep studies evaluation
No baseline dxa scan
No documented testicular exam

-Below minimum

2. Can you form an opinion? Based on your background and experience and review of all information provided you, and assuming that the treatment as documented was provided, can you form an opinion as to whether the care rendered by the care provider, including diagnosis, treatment or record keeping, departed from or failed to conform to the minimal standards of acceptable and prevailing medical practice (in the medical community at large)?

   _____x_ Yes, I can form an opinion.

   _____ No, I cannot form an opinion.

   _____ I need more information (specify): _____

3. What is your opinion? Please use the definitions below as "guidelines" to be used in defining standard of practice. You are not limited to these guidelines in forming your opinion, but please state your own additional criteria if applicable.

   a. Diagnosis. Evaluation of a medical problem using means such as history, physical examination, laboratory, and radiographic studies, when applicable.

      ____x__ Below minimum standards

      _____ Within minimum standards

   b. Treatment. Use of medications and other modalities based on generally accepted and approved indications, with proper precautions to avoid adverse physical reactions, habituation or addiction.

      ____x__ Below minimum standards

      _____

   c. Records.

      Maintenance of records which should contain, at a minimum, the following: (1) appropriate history and physical and/or mental examination for the patient's chief complaint relevant to the physician's specialty; (2) results of diagnostic tests (when indicated); (3) a working diagnosis; (4) notes on treatment(s) undertaken; (5) a record by date of all prescriptions for drugs, with names of medications, strengths , dosages, quantity, and number of refills; and (6) a record of billings.

      Below minimum standards

__x___ Within minimum standards

d. **Overall Opinion. Based on the foregoing, what is your overall opinion?**

_x_____ Clearly below minimum standards.

_____ Clearly within minimum standards

_____ Borderline Case

e. **Gross Ignorance, Gross Negligence, Gross Incompetence. If you found that this physician did not meet the minimum standards of care in treating a patient(s), did you also conclude that any of these departures from the minimum standards of care were so serious that you consider them to exhibit gross ignorance, gross negligence, and/or gross incompetence on the physician's part. If "yes," please identify each of these instances, classify it appropriately and explain your reasoning in reaching that conclusion(s). If "yes," please also indicate whether you found a pattern of gross ignorance, gross negligence and/or gross incompetence in this physician's practice as evidenced by the records reviewed and explain your conclusion(s).**

Gross negligence

Not following standard of care for evaluation and management of testosterone replacement
No clear indication for growth hormone replacement

4. **Explain your opinion. If you opined that practice was below minimum standard for any of the above reasons, state the correct minimal standard of practice (NOTE: It is not sufficient to say "I would have..., or I would have not...", you should be able to testify that "the minimal standard of practice in the medical community at large would be to...") Use extra sheets as necessary to explain your opinion and complete this report.**

There are several major concerns

1. Licensee's narrative mentions patient had been followed by latter for 'multiple years' mentions testosterone level in 100s.
No details available, young male with very low testosterone levels require further work up including details of initial gonadotropins, Pituitary imaging (as indicated) bone density unavailable to establish accurate diagnosis.
Also, what is the value of checking progesterone levels in cis-males? (Cost concerns)

Wide intervals between lab data even when labs were quite high with testosterone levels at 1099 ng/dl
despite skipping injection for 3 weeks. (April 2019)
Hematocrit was quite high.
No dose changes made: dose was not de-escalated
Labs were not repeated until Sep 2019 (5 months later)
And that too only hemoglobin/crit.
No dose change and no testosterone levels
He had acne/folliculitis and was seen by dermatology (likely due to high testosterone levels)
Patient was continued on weekly high dose at 300 mg
On one occasion, injection was even given within 5 days. (6.7.2019 and 6.12.2019)
The testosterone lab values were repeated after 12 months (April 2019 and March 26th, 2020).
During the 1-year period patient probably exposed to very high testosterone levels
Although no labs were done.
March 2020 Levels were again high at 1668 ng/dl along with hematocrit >55 % and hemoglobin >20 gm. No dose change made despite supratherapeutic levels.
Was referred to therapeutic phlebotomy (Ky Blood center).

During this period patient developed respiratory symptoms which continued intermittently with dyspnea, and cough, was treated with bouts of high dose (40 mg x 10 days) glucocorticoids and anti-tussives. Chest Xray showed OGD.
Unsure if was referred to pulmonary or sleep studies given high hematocrit, and dyspnea.
This is a major safety concern.
Hematocrit continued to be high throughout the period reviewed.
After a year, in Jan 2021, dose was decreased to 1 ml with persistent elevated hematocrit.
May 2021, lab showed testo levels at 367 ng/dl
So, dose was increased again to 1.3 ml.
Hematocrit and hemoglobin were still elevated.
The licensee's comments mention that it was unclear why levels were fluctuating.
All levels were high (3). The one level was likely related to glucocorticoids (40 mgx10days) administered from 7 days prior to levels.
Anastrazole use should be monitored with bone profile
(Bod pods are not surrogates for dexa scans)
There were contradicting documentation regarding dose given and that prescribed on few occasions.

#2
Growth Hormone treatment:
No clear indication
Was started on GH based on one low level.
Low SD In obese individuals is well known and is not an indication for replacement.
Also, no dynamic testing performed before starting growth hormone.

#3
Patient has normal a1c (5.1%)
Fasting BG were normal.
No indication for metformin treatment.
While widely may be used for insulin resistance PCOS. prediabetes, type 2 diabetes in this clinical scenario. there was no clear reason.

Summary
Treating patient with high dose of testosterone weekly (much higher than recommended) with no clear indication and evaluation.
No dose de-escalation despite persistent high levels of testosterone and high hematocrit for almost 2 years.
Sometimes Testosterone dose was administered within 5 days.
At one clinic visit, patient received 2.25 ml (7.2020).
No sleep studies or diagnosis of OSA documented.
Persistent pulmonary symptoms requiring frequent steroids, but no evaluation given erythrocytosis induced hypoxia is a major concern.
Unclear indication for growth hormone replacement and no follow up levels once replacement started.
Metformin with no clear indication.
Cjc was recommended by licensee at 12.14.2017 visit.
Cjc is banned and used in dark markers for performance enhancing and other activities.

Ref:
Enclosed.

2. 2. 2022
Date of Review

Signature of Expert

date	labs	Dose -T	Dose somatropin	Rx/comments
12.14.2017	none	77.5 ml 2x weekly	1 iu 5days	cjc
				Anastrazole.
1 11 19	229-32 A1c 5 3% FBG 87 mg/dl IGF-1 105 ng/ml	Plan Testo 150 mg2xweek ,b12 injected 300 mg(1.5ml) at clinic		Metformin Vitals 270 lb bmi 39 87
2.6.19		T 300 mg inj in clinic		
2 13.19		1.5 ml (300 mg)		No vitals
2 20.19	No lab	1.5 ml 300 mg Prednisone, Toradol for Rt LE pain		
2 27.19 3 6 19	No lab	Testo 300 mg		

Tas6

3.13.19 4.10.19				
4.11.2019	1099-302-596 <1100-224-575 (TT-FT-BAT) Hg 18 2(<17.1) Hct 53(<50)	? Comments 3 28 and 3.15 says Kroger vials? ?0 4 ml	Appears testo was skipped for 3weeks to lab draw with high BAT, FT,	
4.172019 4.24.2019 5.1.2019 5.29.2019 6.7.2019 6.12.2019((5 days) 6.19.19 8.7.19 8.21.2019	No T levels	1.5 ml testo at each visit every week and once within 5 days.		
9.12.2019	Hb 18.8 Hct 55 (<50) No T labs			Seen by derm for folliculitis/acne rx doxy
17.4.2019		1 5 ml		
1.2.2020 1.15.20 1.22.20 1.29.20 2.6.20 2.12.20 3 5 2020	No T labs on high dose	1.5 ml/b12		On 3.5.20 treated for pneumonia ,with steroids after testo,l/carnitine injections Chest xray,low temp.3/19 visit
3.26 20	1668-585-1127 Hgb 20, hct 55 9 gm	1 5ml		
4.2.20 4.9.20 4.16.20 4.24.20 4.30.20 5.8.20	Labs as above Glucose 77mg/dl 4.24-5th day inj	1 5 ml		No dose change, still with pulmonary symptoms Was advised blood donation
5.14.20	1222-290-585 19.7-57.4	1.5ml		Same dose Blood donation
Continued weekly 1.5 ml (300 mg) Upto 1.6.21		7.1,2020 –2 25 ml		
1.14.21-5.20.21	19.6/55 1083-203-391 IGF-1 108 ng/ml	1.5 ml		PRBC, switch to 1ml Prednisone rx
1.14.21-5.20.21	19.6/55 1083-203-391 IGF-1 108 ng/ml	1.5 ml		PRBC, switch to 1ml(1/21) Prednisone rx
5.27.21	367-77-148 ,19/56	1ml		Prbc, 1.3 ml

KENTUCKY BOARD OF MEDICAL LICENSURE

EXPERT REVIEW WORKSHEET

(Please type)

Case No.___4____ Patient Name [redacted]
Expert's Name___Sathya Krishnasamy_____

1. Brief description of symptom, dx and course of treatment: _____

56 y male complaining of 'feeling old' and wants to feel younger'. Frequent alcohol use (spirit distributer), recent divorce, c/o myalgias, arthralgias, decreased muscle mass. Labs unavailable however are documented in licensee's visit notes. Based on arrival time, these are likely drawn after 245pm also no repeat labs noted. Also noted patent has hyperlipidemia, normal fasting blood glucose, a1c normal.
IGF-1 116 ng/dl
Started on testosterone high dose 240 mg weekly along with anastrozole, HCG.
Also started on somatropin (HGH) injections.
Metformin and acarbose started for unclear reasons.
Testosterone levels consistently high over 1 year.
Dose mismatch between notes and escribe.
(Refer to table below).
No sleep studies
No dxa scan.
I am concerned about safety of androgen use in patient with incomplete evaluation of androgen deficiency.
Also, HGH use without establishing deficiency is also unsafe.
Patient had higher BG on HGH which is on ethe side effects.

2. Can you form an opinion? Based on your background and experience and review of all information provided you, and assuming that the treatment as documented was provided, can you form an opinion as to whether the care rendered by the care provider, including diagnosis, treatment or record keeping, departed from or failed to conform to the minimal standards of acceptable and prevailing medical practice (in the medical community at large)?

_____x__ Yes, I can form an opinion.

_____ No, I cannot form an opinion.

_____ I need more information (specify): _____

3. What is your opinion? Please use the definitions below as "guidelines" to be used in defining standard of practice. You are not limited to these guidelines in forming your opinion, but please state your own additional criteria if applicable.

   a. Diagnosis. Evaluation of a medical problem using means such as history, physical examination, laboratory, and radiographic studies, when applicable.

      ___x___ Below minimum standards

      _____ Within minimum standards

   b. Treatment. Use of medications and other modalities based on generally accepted and approved indications, with proper precautions to avoid adverse physical reactions, habituation or addiction.

      ___x___ Below minimum standards

      _____ Within minimum standards

   c. Records.

      Maintenance of records which should contain, at a minimum, the following: (1) appropriate history and physical and/or mental examination for the patient's chief complaint relevant to the physician's specialty; (2) results of diagnostic tests (when indicated); (3) a working diagnosis; (4) notes on treatment(s) undertaken; (5) a record by date of all prescriptions for drugs, with names of medications, strengths , dosages, quantity, and number of refills; and (6) a record of billings.

      _____ Below minimum standards

      ___x___ Within minimum standards,

      missing multiple injection logs.

   d. Overall Opinion. Based on the foregoing, what is your overall opinion?

      ___x___ Clearly below minimum standards.

      _____ Clearly within minimum standards

      _____ Borderline Case

   e. Gross Ignorance, Gross Negligence, Gross Incompetence. If you found that this physician did not meet the minimum standards of care in treating a

patient(s), did you also conclude that any of these departures from the minimum standards of care were so serious that you consider them to exhibit gross ignorance, gross negligence, and/or gross incompetence on the physician's part. If "yes," please identify each of these instances, classify it appropriately and explain your reasoning in reaching that conclusion(s). If "yes," please also indicate whether you found a pattern of gross ignorance, gross negligence and/or gross incompetence in this physician's practice as evidenced by the records reviewed and explain your conclusion(s).

_____Gross Ignorance_____

4. Explain your opinion. If you opined that practice was below minimum standard for any of the above reasons, state the correct minimal standard of practice (NOTE: It is not sufficient to say "I would have..., or I would have not...", you should be able to testify that "the minimal standard of practice in the medical community at large would be to...") Use extra sheets as necessary to explain your opinion and complete this report.

Incomplete evaluation for androgen deficiency
Treatment started based on a single PM sample of testosterone
Consistently high levels for over 1 year with no significant dose changes
Discrepancy between visits and injection log doses.
Missing injection logs. (Not submitted)
No sleepstudies
No dexa scan given patient is on anastrazole which can cause low BMD.
No dynamic testing done for growth hormone deficiency
Major safety concerns based on above practice
No clear indication for metformin and acarbose.

2.2.22
Date of Review

Signature of Expert

Table

date	labs	Testo rx	GH rx	comments
2.24.20	No labs TT-FT-BAT-SHBG			Patient wants to feel young wishes to lose 20%fat, bodpod HR 52 Etoh abuse
3.6.2020	Lab sheets not enclosed. Lab values documented by provider, no time mentioned although says arrival time on 3.5.20 is 2:14pm So very likely pM lab draw Testo 428 ng dl Free Test 58 pg	Injected 1.2 ml in clinic (240mg mg testo)on site 0.6 ml 2xweek No cbc data No sleep studies No DXA	Somatrope started 5xweek	No am labs, labs not repeated. Started testo. Statin .HGH, metformin, acarbose, vaseepa, finasteride HCG inj anastrazole
5.27.20 1120am	1715-360-711-30 BG 100	0.8 ml weekly(0.4x2) Documented by pcp however escribe records show 0.5 cc 2xweek	IGF-1 155 Fbg 100	Lipids improved
10.15.20	1493-302-670	Elevated, no dose change Still at 0.5 cc 2xweek		No repeat labs for 7 months
4.8.21	1875-364-748-35	Dose decreased to 0.4 2xweek	IGF-1 190 ng/ml	A1c 5.3%

KENTUCKY BOARD OF MEDICAL LICENSURE

EXPERT REVIEW WORKSHEET

(Please type)

Case No.___5 Patient Name [redacted]
Expert's Name___Sathya Krishnasamy__

1. **Brief description of symptom, dx and course of treatment: __**

64 y male BMI 23.9 kg/m² with hx of HIV. (details of CD 4, viral load, medications unknown) tubulovillous adenoma(polyp), COPD, Peyronie's disease
Was followed by licensee at his previous practice. Based on records appears has been on TRT (testosterone) since 2018, details of initial levels, evaluation, and reason for treatment unclear.
Also, patient is on GH therapy with no established history of growth hormone deficiency.
Does have precancerous polyp (per scope records).
Details of HIV medications, bone density unknown.
No evidence of lipodystrophy on bodpod.

2. **Can you form an opinion? Based on your background and experience and review of all information provided you, and assuming that the treatment as documented was provided, can you form an opinion as to whether the care rendered by the care provider, including diagnosis, treatment or record keeping, departed from or failed to conform to the minimal standards of acceptable and prevailing medical practice (in the medical community at large)?**

____x__ Yes, I can form an opinion.

_____ No, I cannot form an opinion.

_____ I need more information (specify): _____

3. **What is your opinion? Please use the definitions below as "guidelines" to be used in defining standard of practice. You are not limited to these guidelines in forming your opinion, but please state your own additional criteria if applicable.**

   a. **Diagnosis. Evaluation of a medical problem using means such as history, physical examination, laboratory, and radiographic studies, when applicable.**

      ___x___ Below minimum standards

_____ Within minimum standards

b. Treatment. Use of medications and other modalities based on generally accepted and approved indications, with proper precautions to avoid adverse physical reactions, habituation or addiction.

__x___ Below minimum standards

_____ Within minimum standards

c. Records.

Maintenance of records which should contain, at a minimum, the following: (1) appropriate history and physical and/or mental examination for the patient's chief complaint relevant to the physician's specialty; (2) results of diagnostic tests (when indicated); (3) a working diagnosis; (4) notes on treatment(s) undertaken; (5) a record by date of all prescriptions for drugs, with names of medications, strengths , dosages, quantity, and number of refills; and (6) a record of billings.

____x__ Below minimum standards

Within minimum standards.

d. Overall Opinion. Based on the foregoing, what is your overall opinion?

__x____ Clearly below minimum standards.

_____ Clearly within minimum standards

_____ Borderline Case

e. Gross Ignorance, Gross Negligence, Gross Incompetence. If you found that this physician did not meet the minimum standards of care in treating a patient(s), did you also conclude that any of these departures from the minimum standards of care were so serious that you consider them to exhibit gross ignorance, gross negligence, and/or gross incompetence on the physician's part. If "yes," please identify each of these instances, classify it appropriately and explain your reasoning in reaching that conclusion(s). If "yes," please also indicate whether you found a pattern of gross ignorance, gross negligence and/or gross incompetence in this physician's practice as evidenced by the records reviewed and explain your conclusion(s).

_____*Gross Ignorance*_

4. Explain your opinion. If you opined that practice was below minimum standard for any of the above reasons, state the correct minimal standard of practice (NOTE: It is not sufficient to say "I would have..., or I would have not...", you should be able to testify that "the minimal standard of practice in the medical community at large would be to...") Use extra sheets as necessary to explain your opinion and complete this report.

Unclear work up for hypogonadism in patient with underlying chronic immunodeficiency.
Also details of HIV medications unknown.
HIV can cause multiple endocrinopathies including hypopituitarism, HIV adrenal insufficiency, lipodystrophy, and bone loss.
I do not see a clear work up in this case.
Records from prior practice unavailable.
Also, prescribing metformin to patient with history of cachexia and continued weight loss with viral illness is quite concerning.
Why was metformin started given he is lean and BG trends lower?
If patient with HIV is losing weight, there may be several other conditions that will need to be ruled out.
Also, HIV wasting syndrome is associated with advanced HIV (such as AIDS).
Is there a coordination between provider treating HIV regarding this diagnosis of wasting?
Again, use of growth hormone in patient who had recent precancerous lesion does not seem safe although not absolute contraindication.
Also why are progesterone levels checked in all these men?
Is his diagnosis of copd after viral illness early jan-feb 2020 related to covid or other opportunistic infections?
Also, I noted oxandrolone (anabolic steroid) was prescribed April 2019 (escribe record).
No clear reason as to why it was prescribed since it is not approved at this time (except for specific conditions such as burns and cancer cachexia).
Also PEG MGF is unapproved for use and was prescribed once.
Why was hydroxychloroquine recommended? (Intake notes).
The practice trends are quite concerning for safety.

2-1-2022
Date of Review

Signature of Expert

Table

date	labs	Testo rx	comments
5.7.2018 Started weekly 0.75 cc Last dose 7.30 18 before lab draw	None TT-FT-BAT-SHBG	0.75 ml (150 mg) Although make note says 0.3 cc 2xweek	Anastrazole, HCG, HGH HCQ(?)2x2week Tyrosine ultn inj metformin
8/2018 Labs missing after 12/3/2018	[illegible]	0.75 ml	Comments that dose decreased earlier due to aggression and anger. Per injection log dose unchanged
3.4.2019-		1 ml testosterone injection weekly	
6.3.2019	630-36-72-87 (13 days post inj)	Last dose before lab was 5/20 19 However dose increased to 300 mg (1.5 ml	Alk phos 123 Bg 63 Somatrope and testosterone dose increased
11.25 2019	[illegible]	Last dose 10 21.2019	Same dose continued
2.5 20	H/H 16.8 49	1 2 ml Then weekly 1.5 ml weely	Flu like . fatigue, chills,sweating blurred vision.20 lb wt loss, BP 165/95 (COVID?) Alk phos119
5.11.20	No inj since 3/2020	1.5 ml -no further visits until Aug 2020	Covid IgM/G -ve
8/10/20	676-41-85-81		COPD since June 2020
8.17.20		Test 0.3 ml 2xweek However, visits appear to be weekly Last visit 11/2020 No further labs	Metformin HCG Anastrazole Tadalafil Sildenafil

KENTUCKY BOARD OF MEDICAL LICENSURE

EXPERT REVIEW WORKSHEET

(Please type)

Case No.___6 Patient Name_[redacted]
Expert's Name___Sathya Krishnasamy___

1. Brief description of symptom, dx and course of treatment:
50-year male followed by licensee in previous practice. previous drug abuse history, incarcerated for drug trafficking and per narrative patient is drug free since release from prison.
History of class3 obesity, musculoskeletal issues, limb detachment and brachial plexus injury in 2020 requiring prolonged rehab at UofL.
History OSA (2005) urethral strictures requiring dilatation.
Labs from 9/2016 comment as 935 PM
So unclear what time of day labs were drawn.
If these are PM labs, a value of 204 ng testosterone by IA and not MS (method) may not be very reliable.
SHBG was 22 nmol. ALT 48 u/l, indicating likely obesity related low testosterone levels.
I do not see repeat labs to confirm diagnosis before starting testosterone.
Unless 2016 nov labs of ~700 ng/dl were prior to TRT.
Also, labs from 2017 Feb show levels at 1177 ng/dl, with BAT at 786 ng (quite high) and FT at 374 pg/ml(high).
Hgb was 19 gm, HCT 57 %
August 2017 levels were still high at 835 ng/dl
And Hgb continued to climb at 20 gm.
Unclear why dose was not decreased or discontinued.
PSA rose requiring urology evaluation and MRI of prostate.
PSA improved once testosterone was held.
Urology cleared patient to continue testosterone with close observation of PSA, finally dose was reduced from 300 mg weekly to 200 mg weekly.
Was again increased to 300 mg weekly.
Supratherapeutic dose prescribed to patient with OSA, obesity and other co-morbid conditions.

2. Can you form an opinion? Based on your background and experience and review of all information provided you, and assuming that the treatment as documented was provided, can you form an opinion as to whether the care rendered by the care provider, including diagnosis, treatment or record keeping, departed from or failed to conform to the minimal standards of acceptable and prevailing medical practice (in the medical community at large)?

_____x__ Yes, I can form an opinion.

_____ No, I cannot form an opinion.

_____ I need more information (specify): _____

3. What is your opinion? Please use the definitions below as "guidelines" to be used in defining standard of practice. You are not limited to these guidelines in forming your opinion, but please state your own additional criteria if applicable.

   a. Diagnosis. Evaluation of a medical problem using means such as history, physical examination, laboratory, and radiographic studies, when applicable.

      ___x___ Below minimum standards

      _____ Within minimum standards

   b. Treatment. Use of medications and other modalities based on generally accepted and approved indications, with proper precautions to avoid adverse physical reactions, habituation or addiction.

      __x____ Below minimum standards

      _____ Within minimum standards

   c. Records.

      Maintenance of records which should contain, at a minimum, the following: (1) appropriate history and physical and/or mental examination for the patient's chief complaint relevant to the physician's specialty; (2) results of diagnostic tests (when indicated); (3) a working diagnosis; (4) notes on treatment(s) undertaken; (5) a record by date of all prescriptions for drugs, with names of medications, strengths , dosages, quantity, and number of refills; and (6) a record of billings.

      ____ Below minimum standards

      x Within minimum standards,

   d. Overall Opinion. Based on the foregoing, what is your overall opinion?

      __x____ Clearly below minimum standards.

      _____ Clearly within minimum standards

_____ Borderline Case

e. **Gross Ignorance, Gross Negligence, Gross Incompetence. If you found that this physician did not meet the minimum standards of care in treating a patient(s), did you also conclude that any of these departures from the minimum standards of care were so serious that you consider them to exhibit gross ignorance, gross negligence, and/or gross incompetence on the physician's part. If "yes," please identify each of these instances, classify it appropriately and explain your reasoning in reaching that conclusion(s). If "yes," please also indicate whether you found a pattern of gross ignorance, gross negligence and/or gross incompetence in this physician's practice as evidenced by the records reviewed and explain your conclusion(s).**

_____Gross negligence

4. **Explain your opinion. If you opined that practice was below minimum standard for any of the above reasons, state the correct minimal standard of practice (NOTE: It is not sufficient to say "I would have…. or I would have not…", you should be able to testify that "the minimal standard of practice in the medical community at large would be to…") Use extra sheets as necessary to explain your opinion and complete this report.**

Patient in his 40s, obesity 3, OSA, urethral meatus stictures, with low T at initial evaluation
Unclear work up for hypogonadism in patient class 3 obesity.
Did he need pituitary evaluation?
Also was T level repeated before starting treatment.?
I don't see dose of testosterone decreased even when levels and Hemoglobin was persistently high. Rather was referred to donate blood.
Also, PSA levels rose given high testosterone levels requiring urology evaluation and MRI of prostate. (cost burden).
No dxa scan baseline or after starting anastrozole.
Oxandrolone is anabolic steroid abused for performance enhancing and there is no indication for use in this patient.
Prescription of unapproved anabolic steroid with abuse potential to patient with prior history of drug abuse and trafficking is a major concern for patient safety.
Tesofensine is anti-obesity triple reuptake product still under investigation
PEG-MGF is unapproved product for human use.

Also why are progesterone levels checked in all these cis-men?
Once testosterone treatment started, measuring gonadotropins is of not any value. (Cost burden).

2. 21-22

Date of Review

Signature of Expert

KENTUCKY BOARD OF MEDICAL LICENSURE

EXPERT REVIEW WORKSHEET

(Please type)

Case No.___7___ Patient Name_[redacted]___

Expert's Name_____Sathya_Krishnasamy_____

1. Brief description of symptom, dx and course of treatment: _____

Records unavailable pertaining to evaluation prior to 7/2019 visit to current practice location.
Notes from 7.3.2019 mention that 42 y old male patient with HIV treated with Truvada, and Adderall for ADHD (managed by MLM?)
Intake prescriptions include testosterone 2x week, GHRP-6 (GH releasing peptide Ghrelin receptor analog), Follistatin, NP thyroid 30 mg and metformin.
There are no clear details of various diagnoses.
Patient was prescribed clomid, oxandrolone and subsequently patient requested HCG.
Steroids(prednisone) prescribed 3/2021 for likely sports injury.
Labs from Oct 2019, May 2020, Oct 2020, Feb 2021 noted.
Testosterone levels overall stable and within normal limits.
Creatinine elevated, GFR 54, unclear why patient is on metformin 500 mg bid.,
No weight available to assess BMI.
Thyroid function within normal range

2. Can you form an opinion? Based on your background and experience and review of all information provided you, and assuming that the treatment as documented was provided, can you form an opinion as to whether the care rendered by the care provider, including diagnosis, treatment or record keeping, departed from or failed to conform to the minimal standards of acceptable and prevailing medical practice (in the medical community at large)?

_____ Yes, I can form an opinion.

____x___ No, I cannot form an opinion.

_____ I need more information (specify): _____

Why is patient on GHRP-6?
Why is patient on testosterone?
Why is he on follistatin?
Why is he on metformin?

3. **What is your opinion? Please use the definitions below as "guidelines" to be used in defining standard of practice. You are not limited to these guidelines in forming your opinion, but please state your own additional criteria if applicable.**

   a. **Diagnosis. Evaluation of a medical problem using means such as history, physical examination, laboratory, and radiographic studies, when applicable.**

   _____ **Below minimum standards**

   _____ **Within minimum standards**

   Unable to comment due to incomplete records

   b. **Treatment. Use of medications and other modalities based on generally accepted and approved indications, with proper precautions to avoid adverse physical reactions, habituation or addiction.**

   _____x_ **Below minimum standards**

   NO clear indication for GHRP-6 (GH releasing peptide), nandralone (anabolic steroids), follistatin.
   These are unapproved drugs with no clear benefits and no well conducted human studies

   _____ **Within minimum standards**

   c. **Records.**

   Maintenance of records which should contain, at a minimum, the following: (1) appropriate history and physical and/or mental examination for the patient's chief complaint relevant to the physician's specialty; (2) results of diagnostic tests (when indicated); (3) a working diagnosis; (4) notes on treatment(s) undertaken; (5) a record by date of all prescriptions for drugs, with names of medications, strengths , dosages, quantity, and number of refills; and (6) a record of billings.

   _____x_ **Below minimum standards**

   _____ **Within minimum standards**

   d. **Overall Opinion. Based on the foregoing, what is your overall opinion?**

   _____ **Clearly below minimum standards.**

   _____ **Clearly within minimum standards**

___x___ **Borderline Case**

e. **Gross Ignorance, Gross Negligence, Gross Incompetence. If you found that this physician did not meet the minimum standards of care in treating a patient(s), did you also conclude that any of these departures from the minimum standards of care were so serious that you consider them to exhibit gross ignorance, gross negligence, and/or gross incompetence on the physician's part. If "yes," please identify each of these instances, classify it appropriately and explain your reasoning in reaching that conclusion(s). If "yes," please also indicate whether you found a pattern of gross ignorance, gross negligence and/or gross incompetence in this physician's practice as evidenced by the records reviewed and explain your conclusion(s).**

Unable to form an opinion Due to inadequate medical records.

I am certainly concerned about multiple prescriptions including anabolic steroids
Creatinine elevated.
There is mention of renal Ultrasonogram
But nothing about holding metformin (blood sugar in May 2020 labs was low)

Pt is prescribed Truvada, anastrozole
No baseline bone density screening.
Also, I don't see weight < BMI or lipids anywhere despite pt. being on HAART and testosterone prescriptions.
If patient had history of RA (Rheumatoid arthritis), would need Creatinine further investigated to rule our RA related renal disease
Creatinine first elevated May 2020, Oct 2020 and again Feb 2021

Also, no clear indication for anabolic steroids.

4. **Other questions from the Medical Board (ignore if blank):** _____

5. **Explain your opinion. If you opined that practice was below minimum standard for any of the above reasons, state the correct minimal standard of practice (NOTE: It is not sufficient to say "I would have..., or I would have not...", you should be able to testify that "the minimal standard of practice in the medical community at large would be to...") Use extra sheets as necessary to explain your opinion and complete this report.**

We don't have records related to initial evaluation for testosterone replacement and no clear indication for metformin.
However, I have the following concerns:

CKD in patient with HIV and on multiple medications. would need to further evaluation. (May 2020, Oct 2020, Feb 2021)
Also, history of autoimmune disease, will need to evaluate for autoimmune renal disease.
Other concern regarding anabolic steroid prescription.
Ghrelin analog
No lipids, weight, anthropometries available (height noted)
No dxa scan.

2 · 12 · 2022
Date of Review

Signature of Expert

KENTUCKY BOARD OF MEDICAL LICENSURE

EXPERT REVIEW WORKSHEET

(Please type)

Case No.____8__Patient Name__[redacted]___

Expert's Name_Sathya Krishnasamy_____

1. **Brief description of symptom, dx and course of treatment:** _____

male in his late 50s (ED MD). BMI 30.8
Nonspecific symptoms such as fatigue low libido and energy, shift work.
Hashimoto's with high normal TSH.
Elevated transaminases, hyperlipidemia,
Testosterone low normal (time unknown)
Also, no repeat labs before initiating testosterone.
Sleep studies given central adiposity and metabolic syndrome
No details about 59 y old colonoscopy details before initiating GH replacement
And no indication for GH replacement
Patient with family history of GI NET and MGF colon cancer.

Supplements:
Dr Gundry polyphenol
Energy renew
Ashwagandha
Creatin
Seen by nutritionist.

2. **Can you form an opinion? Based on your background and experience and review of all information provided you, and assuming that the treatment as documented was provided, can you form an opinion as to whether the care rendered by the care provider, including diagnosis, treatment or record keeping, departed from or failed to conform to the minimal standards of acceptable and prevailing medical practice (in the medical community at large)?**

_____x__ **Yes, I can form an opinion.**

_____ **No, I cannot form an opinion.**

_____ **I need more information (specify):** _____

3. What is your opinion? Please use the definitions below as "guidelines" to be used in defining standard of practice. You are not limited to these guidelines in forming your opinion, but please state your own additional criteria if applicable.

   a. Diagnosis. Evaluation of a medical problem using means such as history, physical examination, laboratory, and radiographic studies, when applicable.

      ____x_ Below minimum standards

      _____ Within minimum standards

   b. Treatment. Use of medications and other modalities based on generally accepted and approved indications, with proper precautions to avoid adverse physical reactions, habituation or addiction.

      ___x__ Below minimum standards

      _____ Within minimum standards

   c. Records.

      Maintenance of records which should contain, at a minimum, the following: (1) appropriate history and physical and/or mental examination for the patient's chief complaint relevant to the physician's specialty; (2) results of diagnostic tests (when indicated); (3) a working diagnosis; (4) notes on treatment(s) undertaken; (5) a record by date of all prescriptions for drugs, with names of medications, strengths , dosages, quantity, and number of refills; and (6) a record of billings.

      _____ Below minimum standards

      __x___ Within minimum standards

   d. Overall Opinion. Based on the foregoing, what is your overall opinion?

      __x____ Clearly below minimum standards.

      _____ Clearly within minimum standards

      _____ Borderline Case

   e. Gross Ignorance, Gross Negligence, Gross Incompetence. If you found that this physician did not meet the minimum standards of care in treating a patient(s), did you also conclude that any of these departures from the minimum standards of care were so serious that you consider them to exhibit gross ignorance, gross negligence, and/or gross incompetence on the

physician's part. If "yes," please identify each of these instances, classify it appropriately and explain your reasoning in reaching that conclusion(s). If "yes," please also indicate whether you found a pattern of gross ignorance, gross negligence and/or gross incompetence in this physician's practice as evidenced by the records reviewed and explain your conclusion(s).

_____Gross Ignorance__

1. *Repeat um Testo levels before starting replacement*
2. *No Sleep studies*
3. *Was patient on androgen replacement or another supplemental testosterone in the past (LH low) or is there concern for pituitary issues*
4. *BP at initial evaluation was 159/112 mm/hg*

There is 13% increased risk of hypertension
Would be unsafe to start such a high dose 200 mg every week
Without addressing metabolic traits
(Lipids, high BP< sleep studies)

https://www.uptodate.com/contents/testosterone-drug-information?search=testosterone&source=panel_search_result&selectedTitle=1~14&usage_type=panel&kp_tab=drug_general&display_rank=1

The following adverse drug reactions and incidences are derived from product labeling unless otherwise specified.

>10%: Cardiovascular: Hypertension (≤ 13%) (table 1)

5. *GH replacement (growth hormone) without addressing screening colonoscopy in 59 y old male with strong family Dx of GI NET and colon cancer.*
6. *Also, there is no clear benefit in GH replacement without dynamic testing.*

4. **Other questions from the Medical Board (ignore if blank): _____**

5. **Explain your opinion. If you opined that practice was below minimum standard for any of the above reasons, state the correct minimal standard of practice (NOTE: It is not sufficient to say "I would have..., or I would have not...", you should be able to testify that "the minimal standard of practice in the medical community at large would be to...") Use extra sheets as necessary to explain your opinion and complete this report.**

Patient had clear reasons for fatigue

High TPO ab titers
Shift work
Hyperlipidemia
BP elevated

I am concerned that patient was given testosterone without repeating levels.
Also, BP, sleep studies not addressed__.
No bone evaluation before starting anastrozole.
No clear work up for GH.
Also, no screening colonoscopy given family Dx of GI NET and Colon malignancy

2. 18 2022
Date of Review

Signature of Expert

KENTUCKY BOARD OF MEDICAL LICENSURE

EXPERT REVIEW WORKSHEET

(Please type)

Case No.____9_____ Patient Name_[redacted]
Expert's Name_____Sathya Krishnasamy___

1. Brief description of symptom, dx and course of treatment: _____
48 y male with history of Rheumatoid arthritis, evaluated 2.15.2018 for low energy, was not adherent to adalimumab (Humira) therapy (per notes), also on methotrexate/folate and steroids as needed for RA flare
BMI 31.7 kg/m2
Noted has been on suboxone since 2017.
Familial benign tremors on propranolol.
Documented CC is fatigue, weight gain and low energy
We don't have baseline testo levels documented
But was started on 300 mg weekly Testo (very high dose)
Also advised somatropin (growth hormone)
Transaminitis in pt. with autoimmune disease (RA)

2. Can you form an opinion? Based on your background and experience and review of all information provided you, and assuming that the treatment as documented was provided, can you form an opinion as to whether the care rendered by the care provider, including diagnosis, treatment or record keeping, departed from or failed to conform to the minimal standards of acceptable and prevailing medical practice (in the medical community at large)?

__x__ Yes, I can form an opinion.

_____ No, I cannot form an opinion.

_____ I need more information (specify): _____

3. What is your opinion? Please use the definitions below as "guidelines" to be used in defining standard of practice. You are not limited to these guidelines in forming your opinion, but please state your own additional criteria if applicable.

a. Diagnosis. Evaluation of a medical problem using means such as history, physical examination, laboratory, and radiographic studies, when applicable.

_x____ Below minimum standards

_____ Within minimum standards

b. Treatment. Use of medications and other modalities based on generally accepted and approved indications, with proper precautions to avoid adverse physical reactions, habituation or addiction.

____x__ Below minimum standards

_____ Within minimum standards

c. Records.

Maintenance of records which should contain, at a minimum, the following: (1) appropriate history and physical and/or mental examination for the patient's chief complaint relevant to the physician's specialty; (2) results of diagnostic tests (when indicated); (3) a working diagnosis; (4) notes on treatment(s) undertaken; (5) a record by date of all prescriptions for drugs, with names of medications, strengths , dosages, quantity, and number of refills; and (6) a record of billings.

___x___ Below minimum standards

I see 2 rx for testosterone within 4 days
One with dose and amount
Other to Tailor Compounding in Nicholasville.

Not all charts have doses

d. Overall Opinion. Based on the foregoing, what is your overall opinion?

__ ___ Clearly below minimum standards.

_____ Clearly within minimum standards

_____x_ Borderline Case

e. Gross Ignorance, Gross Negligence, Gross Incompetence. If you found that this physician did not meet the minimum standards of care in treating a patient(s), did you also conclude that any of these departures from the minimum standards of care were so serious that you consider them to exhibit gross ignorance, gross negligence, and/or gross incompetence on the

physician's part. If "yes," please identify each of these instances, classify it appropriately and explain your reasoning in reaching that conclusion(s). If "yes," please also indicate whether you found a pattern of gross ignorance, gross negligence and/or gross incompetence in this physician's practice as evidenced by the records reviewed and explain your conclusion(s).

We don't have baseline testosterone levels to comment on.
Interestingly levels not on intake notes either.
Incomplete records.
Gross ignorance based on testosterone dose strength

4. **Other questions from the Medical Board (ignore if blank):** _____

5. **Explain your opinion. If you opined that practice was below minimum standard for any of the above reasons, state the correct minimal standard of practice (NOTE: It is not sufficient to say "I would have..., or I would have not...", you should be able to testify that "the minimal standard of practice in the medical community at large would be to...") Use extra sheets as necessary to explain your opinion and complete this report.**

Given there is no baseline levels, unable to comment on diagnosis.
However, pattern of dosing and lack of dose adjustment for high level are concerning.
Also, no bone health screen prior to anastrazole.
Also, GnRH analog is not indicated for indicated treatment
Some inconsistencies with Rx to Tailor compounding pharmacy (Nicholasville)
No sleep study evaluation for pt. who complains of fatigue.
While we are not clear even if therapy was indicated here, the fact that
Patient has been subsome.
One would be cautious about using controlled substances given pt. has no good compliance with therapy. (Based on narrative).

2.22.2022

Date of Review

Signature of Expert

Table

date	lab	Testo Rx	Other recommended rx supplements	comments
2.15.18	Testo levels not documented Elevated ALT/AST	1 cc glut inj	Metformin HcG HGH Anastrazole Finasteride B12	No sleep study eval for fatigue
3.8.18	Levels not documented	0.75 cc 2xweek		Elevated bP not addressed 151/93 before starting injections.
5.24.2018	217 ng TPO titers 75	Same dose		Didn't take shot x3weeks. Also recent steroids
10.2018	T 1107 ng/dl IA (250-827) BAT 670 (110-575) Free T 340 pg/ml (46-224) Shbg 14 nmol/l	No change in dose	Given metformin and anastrozole	
1.31.2019	Total 933 IA Free 241 BAT 486	Testo 0.6 ml every 5 days (120 mg	HCG	
7.3.2019	Total:1630 Free testo 534 1030(110-575)	Testo 0.5 ml 2xweek (higher dose)	HCG	Unclear why LH,FSH ,progesterone
1.23.20	Total 840 Free 196 395	Dose not mentioned		
5.2020	1076, Free 278.9 BAT 537	No dose change		
12.20	644 134 258	Testo 0.5 ml 2xweek		Ldl 128, elevated homocysteine,pLA2.CRP
3.2021		Gonadorelin inj		GnRH analog used for HPA testing axis limited use and in veterinary medicine

KENTUCKY BOARD OF MEDICAL LICENSURE

EXPERT REVIEW WORKSHEET

(Please type)

Case No._____10____ Patient Name__[redacted]

Expert's Name_____Sathya Krishnasamy_____

1. **Brief description of symptom, dx and course of treatment:** _____

61 y male followed by his PCP for TRT x 7 years (unclear etiology and work up)
2020 Jan labs have no T levels (prior to initiation)
He was started on T injections at initial visit and continued 0.5 cc 2x week (200 mg weekly
Followed by urology for family history of prostate cancer

2. **Can you form an opinion? Based on your background and experience and review of all information provided you, and assuming that the treatment as documented was provided, can you form an opinion as to whether the care rendered by the care provider, including diagnosis, treatment or record keeping, departed from or failed to conform to the minimal standards of acceptable and prevailing medical practice (in the medical community at large)?**

_____ **Yes, I can form an opinion.**

_____x__ **No, I cannot form an opinion.**

_____ **I need more information (specify):** _____

3. **What is your opinion? Please use the definitions below as "guidelines" to be used in defining standard of practice. You are not limited to these guidelines in forming your opinion, but please state your own additional criteria if applicable.**

   a. **Diagnosis. Evaluation of a medical problem using means such as history, physical examination, laboratory, and radiographic studies, when applicable.**

   Since patient was followed by a different provider it is unclear why he was started on testosterone at age 53 y.

   _____ **Below minimum standards**

_____ Within minimum standards

b. Treatment. Use of medications and other modalities based on generally accepted and approved indications, with proper precautions to avoid adverse physical reactions, habituation or addiction.

_____ Below minimum standards

The dose of testosterone 200 mg weekly is quite high
Also, no sleep apnea evaluation
Anastrozole -no bone screen
Also pt. is 61 y old with no screening colonoscopy
Why was GH initiated?

_____ Within minimum standards

c. Records.

Maintenance of records which should contain, at a minimum, the following: (1) appropriate history and physical and/or mental examination for the patient's chief complaint relevant to the physician's specialty; (2) results of diagnostic tests (when indicated); (3) a working diagnosis; (4) notes on treatment(s) undertaken; (5) a record by date of all prescriptions for drugs, with names of medications, strengths , dosages, quantity, and number of refills; and (6) a record of billings.

_____ Below minimum standards

__X__ Within minimum standards

d. Overall Opinion. Based on the foregoing, what is your overall opinion?

__X__ Clearly below minimum standards.

_____ Clearly within minimum standards

_____ Borderline Case

e. Gross Ignorance, Gross Negligence, Gross Incompetence. If you found that this physician did not meet the minimum standards of care in treating a patient(s), did you also conclude that any of these departures from the minimum standards of care were so serious that you consider them to exhibit gross ignorance, gross negligence, and/or gross incompetence on the physician's part. If "yes," please identify each of these instances, classify it appropriately and explain your reasoning in reaching that conclusion(s). If

"yes," please also indicate whether you found a pattern of gross ignorance, gross negligence and/or gross incompetence in this physician's practice as evidenced by the records reviewed and explain your conclusion(s).

____Ignorance___

High dose weekly testosterone
No sleep studies or bone health screen
GH initiated without screening scope.
No clear reason for adult GH replacement.

4. Other questions from the Medical Board (ignore if blank): _____

5. Explain your opinion. If you opined that practice was below minimum standard for any of the above reasons, state the correct minimal standard of practice (NOTE: It is not sufficient to say "I would have…, or I would have not…", you should be able to testify that "the minimal standard of practice in the medical community at large would be to…") Use extra sheets as necessary to explain your opinion and complete this report.

high dose testosterone (200 mg weekly)
Sleep studies missing
GH initiated without screening colonoscopy in 60 y old male and no clear reason for replacement

2.22.2022

Date of Review

Signature of Expert

KENTUCKY BOARD OF MEDICAL LICENSURE

EXPERT REVIEW WORKSHEET

(Please type)

Case No._____11_____ Patient Name___ [redacted]
Expert's Name_____Sathya Krishnasamy_____

1. Brief description of symptom, dx and course of treatment:
59 y male seen in 4.16. 2018. Medical history significant for HIV.
On Atripla
BMI 23.67.
No baseline labs shared. started on testosterone
Does not fit wasting syndrome description.
Also was prescribed anastrozole (no dxa scan)
Advised blood donation.
No dose adjustments. also visits were not regular.

2. Can you form an opinion? Based on your background and experience and review of all information provided you, and assuming that the treatment as documented was provided, can you form an opinion as to whether the care rendered by the care provider, including diagnosis, treatment or record keeping, departed from or failed to conform to the minimal standards of acceptable and prevailing medical practice (in the medical community at large)?

____x___ Yes, I can form an opinion.

_____ No, I cannot form an opinion.

_____ I need more information (specify): _____

3. What is your opinion? Please use the definitions below as "guidelines" to be used in defining standard of practice. You are not limited to these guidelines in forming your opinion, but please state your own additional criteria if applicable.

a. Diagnosis. Evaluation of a medical problem using means such as history, physical examination, laboratory, and radiographic studies, when applicable.

____x_ Below minimum standards
Labs missing from initial evaluation
No testicular exam

_____ Within minimum standards

b. Treatment. Use of medications and other modalities based on generally accepted and approved indications, with proper precautions to avoid adverse physical reactions, habituation or addiction.

____X__ Below minimum standards

_____ Within minimum standards

c. Records.

Maintenance of records which should contain, at a minimum, the following: (1) appropriate history and physical and/or mental examination for the patient's chief complaint relevant to the physician's specialty; (2) results of diagnostic tests (when indicated); (3) a working diagnosis; (4) notes on treatment(s) undertaken; (5) a record by date of all prescriptions for drugs, with names of medications, strengths , dosages, quantity, and number of refills; and (6) a record of billings.

_____ Below minimum standards

____X__ Within minimum standards

d. Overall Opinion. Based on the foregoing, what is your overall opinion?

___X___ Clearly below minimum standards.

_____ Clearly within minimum standards

_____ Borderline Case

e. Gross Ignorance, Gross Negligence, Gross Incompetence. If you found that this physician did not meet the minimum standards of care in treating a patient(s), did you also conclude that any of these departures from the minimum standards of care were so serious that you consider them to exhibit gross ignorance, gross negligence, and/or gross incompetence on the physician's part. If "yes," please identify each of these instances, classify it appropriately and explain your reasoning in reaching that conclusion(s). If "yes," please also indicate whether you found a pattern of gross ignorance, gross negligence and/or gross incompetence in this physician's practice as evidenced by the records reviewed and explain your conclusion(s).

Gross Ignorance

4. Other questions from the Medical Board (ignore if blank): _____

5. **Explain your opinion. If you opined that practice was below minimum standard for any of the above reasons, state the correct minimal standard of practice (NOTE: It is not sufficient to say "I would have..., or I would have not...", you should be able to testify that "the minimal standard of practice in the medical community at large would be to...") Use extra sheets as necessary to explain your opinion and complete this report.**

No indication for anabolic steroids, testosterone and HGH in patient with HIV.
BMI 23.8
Does not fit definition of wasting syndrome given he does have advanced HIV/AIDS.
Unapproved performance enhancing drugs such as PEG-MGF (mechano-growth factor pegylated-inj)

There was one occasion with low T levels in Feb 2019
However, it was after withdrawal from androgen and recent prescription of opioids (1/21/19)
The other low normal lab was drawn at PM after 5-month break from TRT.
No dxa scan for pt. with HIV on anastrozole.
Very concerning is recommendation of hydroxychloroquine in patient with HIV for Covid-virus (for a cost of $220) (In intake handwritten notes).
Not standard of care during specially during pandemic.

2.22.2022

Date of Review

Signature of Expert

Table

date	labs	Testo rx	Other agents	comments
4.16.18	Not shared	Given 1 ml and started on 0.4 ml 2xweek (180 mg weekly)	Started oxandrolone(AAS) Anastrazole PFC(hCG) Metformin Ommitrope (HGH)	
4.24 2018	Hgb 18 gm(note) Hs-crp 66 No lab copies	Testo 1ml weekly(200 mg)		Advised blood donation Dhea-s Fish oil D
Weekly	No labs	1 ml weekly until 10.1.2018		
10.22.2018	Total 697 (no 1 inj x 21 days) Free 94.9 Hgb 18.9 gm Hct 53	No change in dose Last dose weekly until 12 17 18		
2 5 2019	279 34 35 Hgb 17.6 Hct 50	Continue weekly 1 ml		1.21.19 hydroxyzine
6.10 2019	Total 770 Free 154	Weekly Until 3 19 20	Start HCG	Non hormone Labs d/b pcp. started lisinopril by pcp no lab copies
8.11.20 166 lb 23.8 bMI	410(2pm) 36 50 h/h 17/47	Resume testo 0.4 x2 weekly	HCG Anastrazole metformin	Consider HCQ,[covid?]N220 Rapamycin, thymosin

KENTUCKY BOARD OF MEDICAL LICENSURE

EXPERT REVIEW WORKSHEET

(Please type)

Case No.____ 12 _____ Patient Name_[redacted]
Expert's Name_____Sathya Krishnasamy_____

1. **Brief description of symptom, dx and course of treatment:** _____
32 y male with hx CVA in teen years (boxing injury? TBI? hypercoagulable state) And metabolic syndrome.
On propranolol for hypertension. (Not best choice of antihypertensive)
Decreased energy, weight gain., anxiety. Seen 9.2018
BMI 33 kg/M2
Labs show testosterone in mid 200s (IA) but low SHBG
Started on 1½ ml (300 mg) weekly
No sleep studies.
No bone screen(anastrazole)

2. **Can you form an opinion? Based on your background and experience and review of all information provided you, and assuming that the treatment as documented was provided, can you form an opinion as to whether the care rendered by the care provider, including diagnosis, treatment or record keeping, departed from or failed to conform to the minimal standards of acceptable and prevailing medical practice (in the medical community at large)?**

   _____x_ Yes, I can form an opinion.

   _____ __ No, I cannot form an opinion.

   _____ I need more information (specify): _____

3. **What is your opinion? Please use the definitions below as "guidelines" to be used in defining standard of practice. You are not limited to these guidelines in forming your opinion, but please state your own additional criteria if applicable.**

   a. **Diagnosis. Evaluation of a medical problem using means such as history, physical examination, laboratory, and radiographic studies, when applicable.**

      __x___ Below minimum standards
      _____ Within minimum standards

b. Treatment. Use of medications and other modalities based on generally accepted and approved indications, with proper precautions to avoid adverse physical reactions, habituation or addiction.

___x___ Below minimum standards

_____ Within minimum standards

c. Records.

Maintenance of records which should contain, at a minimum, the following: (1) appropriate history and physical and/or mental examination for the patient's chief complaint relevant to the physician's specialty; (2) results of diagnostic tests (when indicated); (3) a working diagnosis; (4) notes on treatment(s) undertaken; (5) a record by date of all prescriptions for drugs, with names of medications, strengths , dosages, quantity, and number of refills; and (6) a record of billings.

_____ Below minimum standards

____x__ Within minimum standards

d. Overall Opinion. Based on the foregoing, what is your overall opinion?

___x___ Clearly below minimum standards.

_____ Clearly within minimum standards

_____ Borderline Case

e. Gross Ignorance, Gross Negligence, Gross Incompetence. If you found that this physician did not meet the minimum standards of care in treating a patient(s), did you also conclude that any of these departures from the minimum standards of care were so serious that you consider them to exhibit gross ignorance, gross negligence, and/or gross incompetence on the physician's part. If "yes," please identify each of these instances, classify it appropriately and explain your reasoning in reaching that conclusion(s). If "yes," please also indicate whether you found a pattern of gross ignorance, gross negligence and/or gross incompetence in this physician's practice as evidenced by the records reviewed and explain your conclusion(s).
Ignorance

4. Other questions from the Medical Board (ignore if blank): _____

5. **Explain your opinion. If you opined that practice was below minimum standard for any of the above reasons, state the correct minimal standard of practice (NOTE: It is not sufficient to say "I would have..., or I would have not...", you should be able to testify that "the minimal standard of practice in the medical community at large would be to...") Use extra sheets as necessary to explain your opinion and complete this report.**

32 y male with hx CVA in high school (unclear etiology, TBI vs hypercoagulable state, with hypertension, Obesity, dyslipidemia
High risk for recurrent CVD.
No repeat testosterone levels before starting treatment
Other traits of true hypogonadism such as decreased body hair, decreased testicular volume, not documented.
Also sleep studies not done given BMI and symptoms (no documentation of OSA diagnosis) If patient was already diagnosed, was not listed in his medial history
No indication for Growth hormone
Licensee recommended ipamorelin and also ejc 1295(banned products used in grey markets).
If addressing overall health, BP medication choice, lipid intervention should have been addressed
No bone health screen prior to anastrazole use.
Also recommendation to donate blood is not standard of care
Dose adjustments would be the logical next step.

2.22.2022

Date of Review

Signature of Expert

date	labs	Testo dose	comments
9.19.2018	Total 233 (IA) SHBG 11 Ldl 119 Tgl 264	Testo 1.2 ml/week	Anastrazole Metformin B12/I Ipamorelin/ejc-1295 Phentermine HCG
10.31.18	Total 862 Free 230	Same dose.	Anastrazole increased for mastalgia
2.20.2019	898 (250-1100) MS 256 pg/ml(46-224)	Same dose	
7.24.2019	1125 306 pg/ml	Decrease to 1 ml (from 1.2) Donate blood	