

WIDENER UNIVERSITY SCHOOL OF LAW

HEALTH LAW II

MIDTERM EXAM

Professor Pope

Spring 2011

GENERAL INSTRUCTIONS:

1. **Read Instructions:** You may read these instructions (the first three pages of this exam packet) *before* the official time begins.
2. **Honor Code:** While you are taking this exam, you may not discuss it with anyone.
3. **Competence:** Accepting this examination is a certification that you are capable of completing the examination. Once you have accepted the examination, you will be held responsible for completing the examination.
4. **Exam Packet:** This exam consists of **nine (9) pages**, including this cover page. Please make sure that your exam is complete.
5. **Identification:** Write your exam number in four places: (1) Write it in the space provided in the upper-right hand corner of this page. (2) Write your exam number on the cover of each Bluebook (or your ExamSoft file) that you use for Part Two. (3) Write your exam number (*and* fill in the corresponding ovals) on the Scantron form. (4) Write your exam number on the upper-right-hand corner of your envelope.
6. **Anonymity:** The exams are graded anonymously. Do *not* put your name or anything else that may identify you (except for your exam number) on the exam.
7. **Timing:** This exam must be completed within seventy-five (75) minutes.
8. **Scoring:** There are 60 points on the exam. The exam is written and graded as a 60-point, 60-minute exam. But you have 75 minutes in which to complete the exam. Thus, you have 15 extra “buffer” minutes.
9. **Open Book:** This is an OPEN book exam. You may use *any* written materials, including, but not limited to: any required and recommended materials, any handouts from class, PowerPoint slides, class notes, and your own personal or group outlines. You may not use a computer other than in its ExamSoft mode.
10. **Format:** The exam consists of two parts which count toward your grade in proportion to the amount of time allocated.

PART ONE comprises 8 multiple choice questions worth two points each, for a *combined* total of 16 points. The suggested total completion time is **16 minutes**.

PART TWO comprises one essay question worth 44 points. The suggested completion time is **44 minutes**.

- 11 **Grading:** All exams will receive a raw score from zero to 60. The raw score is meaningful only relative to the raw score of other students in the class. For example, if the highest raw score in the class were 40 of 60, then that student would typically receive an “A.” The only “real” letter grade is that computed at the end of the course by summing the midterm, final, and quiz scores. But for your informational purposes only, I will estimate a letter grade for your midterm. Your raw score will be converted into a scaled score, based on the class curve. (There are two separate curves: one for M.J. students and one for J.D. and LL.M. students. The applicable mandatory curve in this class permits a maximum average grade of 3.40 for the J.D. students.) I will post an explanatory memo and a model answer to TWEN a few weeks after the exam.
- 12 **Special Instructions:** Instructions specific to each exam section are printed immediately below.

SPECIAL INSTRUCTIONS FOR PART ONE:

1. **Format:** This Part contains 8 multiple choice questions, worth two points each, for a combined total of 16 points. This part has a suggested completion time of 16 minutes. Please note that the questions vary in both length and complexity. You might answer some in 20 seconds and others in two minutes.
2. **Identification:** Write your Student ID *both* on the first page of this exam booklet. *and* on the Scantron form. Fill in the corresponding ovals.
3. **Fill the Oval on the Scantron:** For each question, *fill in* the oval on the Scantron corresponding to the *best* answer choice.
4. **Ambiguity:** If (and only if) you believe the question is ambiguous, such that there is not one obviously best answer, neatly explain why in a separately marked section of your Bluebook or ExamSoft file. Your objection must (i) identify the ambiguity or problem in the question and (ii) reveal what your answer would be for all possible resolutions of the ambiguity. I do *not* expect this to be necessary.

SPECIAL INSTRUCTIONS FOR PART TWO:

1. **Submission:** Write your *essay* answers in your Bluebook examination booklets or ExamSoft file. I *will not* read any material which appears only on scrap paper.

2. **Legibility:** Write legibly. I will do my best to read your handwriting, but must disregard (and not give you points for) writing that is too small to read or otherwise illegible. *I am serious; write neatly.*
3. **Outlining Your Answer:** I strongly encourage you to use *at least* one-fourth of the allotted time per question to outline your answers on scrap paper *before* beginning to write in your exam booklet or ExamSoft file.

Do this because you will be graded not only on the substance of your answer but also on its clarity and conciseness. In other words, organization, precision, and brevity count. If you run out of insightful things to say about the issues raised by the exam question, stop writing until you think of something. Tedious repetition, regurgitations of law unrelated to the facts, or rambling about irrelevant issues *will* negatively affect your grade.

4. **Answer Format:** This is important. *Use headings and subheadings.* Use short single-idea paragraphs (leaving a blank line between paragraphs).
5. **Answer Content:** Address *all* relevant issues that arise from and are implicated by the fact pattern and that are responsive to the “call” of the question. Do not just summarize all the facts or all the legal principles relevant to an issue. Instead, *apply* the law you see relevant to the facts you see relevant. Take the issues that you identify and organize them into a coherent structure. Then, within that structure, examine issues and argue for a conclusion.
6. **Citing Cases:** You are welcome but *not* required to cite cases. While it is sometimes helpful to the reader and a way to economize on words, do not cite case names as a complete substitute for legal analysis. For example, do *not* write: “Plaintiff should be able to recover under *A v. B.*” Why? What is the rule in that case? What are the facts in the instant case that satisfy that rule?
7. **Cross-Referencing:** You may reference your own previous analysis (*e.g.* B’s claim against C is identical to A’s claim against C, because __.” But be very clear and precise what you are referencing. As in contract interpretation, ambiguity is construed against the drafter.
8. **Balanced Argument:** Facts rarely perfectly fit rules of law. So, recognize the key weaknesses in your position and make the argument on the other side.
9. **Additional Facts:** If you think that an exam question fairly raises an issue but cannot be answered without additional facts, state clearly those facts (reasonably implied by, suggested by, or at least consistent with, the fact pattern) that you believe to be necessary to answer the question.

STOP !

**Do NOT turn this page
until the proctor signals**

PART ONE

8 questions worth two points each = 16 points
Suggested Time = 16 minutes

1. **Which of the following are POTENTIAL penalties for violation of Stark self referral laws?**
 - A. Denial of payment; mandatory refund of any payments previously received.
 - B. Civil money penalties of up to \$15,000 per prohibited referral.
 - C. Exclusion from the Medicare and Medicaid programs.
 - D. "Circumvention schemes" are punishable by civil money penalties of up to \$100,000 per scheme.
 - E. All of the above.

2. **The _____ prohibits knowingly and willfully making payments either in return for patient referrals or to induce the purchasing or leasing of equipment or services paid for by federal programs.**
 - A. False Claims Act
 - B. Stark Law
 - C. HCQIA
 - D. Anti-Kickback Law
 - E. NLRA

3. **A physician group that refers many Medicare patients to various community labs for clinical laboratory services has decided to open a lab of their own -- but in their spouses' names. The plan was simple: (1) operate an off-site lab, (2) refer all their patients to that lab, and (3) enjoy the profits from all the business they refer to the lab. Is this referral arrangement lawful under Stark?**
 - A. Yes. Stark only prohibits physicians from referring patients for designated health services at entities in which they have a financial relationship. These physicians do not personally have a financial relationship with the new lab.
 - B. Yes. Lab services are not a "designated health service."
 - C. Both A and B.
 - D. No. This arrangement is prohibited by Stark.

4. **In order for either a space or equipment lease to qualify as an exception under the Anti-Kickback Statute, all of the following must be true EXCEPT:**
- A. The rental amount must be fair market value.
 - B. The term cannot be for less than two years.
 - C. The lease must in writing and signed by both parties.
 - D. The lease must specify the premises and equipment covered by the lease.
5. **The _____ is a federal statute that covers fraud involving any federally funded contract or program, and establishes civil liability for any person who knowingly presents or causes to be presented a false or fraudulent claim for payment by the U.S. government.**
- A. Anti-Kickback Statute
 - B. Stark Law
 - C. False Claims Act
 - D. HCQIA
 - E. National Labor Relations Act
6. **In March 2010, Hospital hired Physician. But within a few months, concerns about Physician's radiological competency surfaced. In May 2010, Physician failed to diagnose one patient's case of appendicitis, did not recognize a colon abnormality that turned out to be cancerous for a second patient, and failed to indicate a liver abnormality in a third patient. After following standard internal processes, the Hospital terminated Physician's employment contract and privileges. Must the Hospital report this action to the NPDB?**
- A. No, this is not a professional review action.
 - B. No, this does not involve malpractice payments.
 - C. Yes, this must be reported.
 - D. Yes, this must be reported, if the Hospital wants to retain its civil money damages immunity.

Please use the following fact pattern for BOTH Questions 7 and 8.

In an effort to increase the number of cardiothoracic patients referred to U-Med, U-Med engaged in a cardiology recruitment initiative. U-Med entered into employment contracts with local community cardiologists in private practices who had patients whom they could refer to U-Med. These cardiologists were contracted to work part-time at U-Med as Clinical Assistant Professors, performing various services for U-Med including teaching, lecturing and research.

Pursuant to one CAP contract, community cardiologist Dr. Gugg received an annual salary of \$75,000. In fact, Gugg was never actually required to perform the duties of a CAP. U-Med billed Medicare over \$250,000 for cardiac-related medical procedures performed on patients referred from Dr. Gugg.

7. U-Med has probably violated:

- A. Anti-Kickback Statute
- B. Stark Law
- C. False Claims Act
- D. A and B
- E. A and B and C

8. Suppose the government proceeds against not only U-Med but also against Gugg. What is the MOST LIKELY reason that the government could not get summary judgment on a Stark claim?

- A. Gugg fits within the “bona fide employee” exception to Stark.
- B. The analysis of whether U-Med acted “knowingly” is a determination regarding his state of mind. It is a fact question that must go to the jury.
- C. Gugg has no “financial relationship” with U-Med.
- D. There is no reason that the Court could not grant summary judgment.

PART TWO

1 essay question worth 44 points

Suggested time = 44 minutes

Between June 2008 and June 2010, Tess was a nurse at Wilmington Dialysis Clinic (WDC). She supervised the on-site dialysis treatments that were provided during her shift. Dialysis is a blood filtration system that replaces the function of the kidneys. Most dialysis treatment is paid for by the Medicare program. Indeed, during this two year time period, WDC billed Medicare \$4.4 million (300 treatments per week, at \$140 each).

The Manager of WDC owned two limited liability companies (WD-1 LLC and WD-2 LLC). In 2009, Manager decided to run WDC through WD-2 rather than through WD-1. Accordingly, on behalf of WD-2, Manager filed and signed a new CMS form 855A, which is a 42-page Medicare Enrollment Application for institutional providers. Page 37 of that form provides in part:

I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

Tess has told you that the medical services WDC provided during her employment were deficient. She saw WDC systematically violate proper dialysis procedures: (i) by failing to provide adequate staffing, (ii) by permitting medication to be administered by unqualified personnel (e.g. technicians instead of nurses), and (iii) by permitting contamination of medications and supplies. These violations materially compromised patient health care on at least thirteen specific occasions of which Tess is aware.

Your research uncovered several statutes and regulations *potentially* relevant to Tess' concerns. 42 U.S.C. § 1395y(a)(1)(A) provides:

No payment may be made under [the Medicare statute] for any expenses incurred for items or services which . . . are not . . . necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

42 U.S.C. § 1320c-5(b) provides that if CMS determines that a provider has “failed in a substantial number of cases” to comply with the requirements of Section 1320c-5(a) or that the provider has “grossly and flagrantly violated” that section, then CMS may exclude the provider from continued eligibility in the Medicare program.

42 U.S.C. § 1320c-5(a) provides:

It shall be the obligation of any health care practitioner . . . who provides health care services for which payment may be made . . . to assure, to the extent of his authority that services or items ordered or provided by such practitioner . . . (2) will be of a quality which meets professionally recognized standards of health care

Finally, Section 494 of Title 42 of the *Code of Federal Regulations* is entitled “Conditions for Coverage for End-Stage Renal Disease Facilities.” The first section (42 C.F.R. § 494.1) provides: “the provisions of this part establish the conditions for . . . determining whether an ESRD facility [may participate in the Medicare program].” Three subsequent sections are also *potentially* relevant. 42 C.F.R. § 494.180(b) mandates that “an adequate number of qualified personnel [be] present whenever patients are undergoing dialysis.” 42 C.F.R. § 494.140 requires that “dialysis facility staff must meet the applicable scope of practice board licensure requirements.” And 42 C.F.R. § 494.30 requires that the “dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents.”

You are *qui tam* counsel for Tess. Please assess the merits of any False Claims Act claim(s) that Tess can bring against the Manager of WDC. You need not address procedural issues.

Multiple Choice Questions

Question	Correct	% class	Explanation	Points	Earned
1	E			2	
2	D			2	
3	D			2	
4	B			2	
5	C			2	
6	D			2	
7	E			2	
8	D			2	
TOTAL				16	

Essay Question

NOTE: This problem was adapted from *Blundell v. Dialysis Clinic, Inc.*, No. 5:09-CV-00710 (N.D.N.Y. Jan. 19, 2011).

	Issue	P	E
Claims			
Claims made	The clinic submitted thousands of claims totaling millions of dollars.	3	
Federal payer	The claims were made to Medicare, a federal payer.	3	
Falsity			
Factual falsity: Worthless service	Given the violation of numerous quality standards, it is plausible that the quality of the dialysis was so poor that it was tantamount to no dialysis at all. On the given facts, it is unclear if the quality deteriorated quite this far. But the theory may work at least in the thirteen instances where patients were harmed.	6	
Legal falsity: Express certification	The defendant signed the 855A form. Moreover, he signed it during the relevant time period. By signing and submitting this form, the defendant promised or “certified” expressly (in writing) that he would comply with all Medicare laws and regulations (both conditions of payment and conditions of participation).	5	
	The defendant did not comply with 1320c-5 due to the low quality care (staffing, licensure, and contamination) .	3	
	The defendant arguably did not comply with 494.180 due to low staffing levels.	3	
	The defendant arguably did not comply with 494.140 licensure requirements due to technicians (rather than nurses) providing treatments for which they were not licensed.	3	
	The defendant arguably did not comply with 494.30 due to unsanitary conditions.	3	
Legal falsity: Implied certification	The above-mentioned regulations were arguably violated. But implied false certification is not a viable theory of falsity. It should be analyzed only to be dismissed.	--	--
	The above-mentioned regulations do not condition payment on compliance. They focus only on continued <i>participation</i> in the Medicare program. Violation does not affect <i>payment</i> . Indeed, violation of 1320 does not even affect participation unless and until it is “flagrant.”	5	
	In contrast, 1395y does condition payment on compliance. We saw this provision in <i>Mikes</i> . It is the right <i>type</i> of statute that can support an implied certification theory of falsity. But here, as in <i>Mikes</i> , the facts do not indicate that the provision was violated. Tess’ complaints are about the quality of the dialysis. She has not alleged that it was provided to patients who did not need it in the first place.	5	
Knowingly			
Plausible Inference	While there is no evidence of deliberate fraud, the scope and ongoing nature of the violations suggests that the defendant was either reckless or consciously indifferent. Even if he did not know about the statutory and regulatory violations, he <i>should have known</i> because of a duty to monitor staffing and quality. Under the circumstances, any ignorance is likely due not to mere negligence but to recklessness.	5	
Total		44	

Midterm Exam Scores – Health Law II (Spring 2011)

SSN	MULTIPLE (16)	ESSAY (44)	TOTAL (60)
209325	14	21	35
328677	12	17	29
400374	14	9	23
466507	12	19	31
528996	12	2	14
546771	12	17	29
603424	14	14	28
605861	14	32	46
605881	14	17	31
606066	12	21	33
608760	12	8	20
622619	14	18	32
652177	16	23	39
665354	16	29	45
680061	14	25	39
680123	12	9	21
683636	12	26	38
685652	16	16	32
700128	14	14	28
705578	14	16	30
709768	14	23	37
721007	16	22	38
721309	14	18	32
741083	16	25	41
761832	10	25	35
764115	14	19	33
783352	12	10	22
786767	16	11	27
846752	16	25	41

Range = 14 to 46

Average = 32