SOCIAL AND ADMINISTRATIVE PHARMACY
PHARMACEUTICAL ECONOMICS AND POLICY (SAPh 8235)

Fall Semester 2019

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Class Hours: Tuesday, 1:00 – 3:00 p.m.

Classroom: 7-173 WDH

Credit Hours: 3.0

Catalog Description: Economic and policy analysis of the pharmaceutical sector of the health care system. Problems of pricing, production, and distribution of pharmaceuticals. Domestic and international policy issues relevant to price and access of pharmaceuticals.

Course Objectives:

1. Describe the structure, conduct, and recent performance of the US pharmaceutical industry.
2. Describe the drug approval process and its impact on pharmaceutical R&D.
3. Describe the intent and function of regulations bearing on the pharmaceutical industry in the US and abroad.
4. Discuss managed care and its relation to the development and pricing of pharmaceuticals.
5. Discuss current trends and public policy relevant to the promotion of pharmaceuticals in the US.
6. Explain the process of public policy formation, implementation, and evaluation.
7. Apply the public policy process to issues in the pharmaceutical market.
8. Understand the historical events that influenced and shaped current pharmaceutical policies

Required Readings: Class readings will and links will be posted to Canvas prior to class. Completing the readings will likely require 3 - 5 hours of your time (sometimes more) each week. Much of the learning in this course will be done independently through assigned readings. Class or discussion time will complement, but not replace, the material presented in these readings. The readings should be viewed as an opportunity to explore complicated topics, critically appraise the evidence regarding different pharmaceutical policies, and explore more deeply than what is covered in lecture format the areas related to each topic. You are required to complete the readings each week and must come prepared to discuss these readings in class.

Course Philosophy: Pharmaceutical policy is a major factor in developing and evolving the delivery of health care. This course will help student develop an understanding of pharmaceutical policy and its relationship to the health of patients, delivery of health care, and influence on the health care system. A broad understanding of these relationships is critical for student seeking careers in health related fields including academia, the pharmaceutical industry, managed care, health consulting, and/or governmental health organizations. Given the influence of pharmaceutical policy on the health of patients, it is also critical for students pursuing research foci in both quantitative and qualitative fields of health care. By necessity, the course will focus on breadth, not depth, in each area. A complete course could easily be taught on many of the individual topics discussed in the course.

Each week we will read from a variety of sources; some didactic, others empirical. These sources will often present differing viewpoints, conceptualizations, opinions, etc. regarding the week's topic. The overarching goal of this course is to help you to develop critical thinking skills in the area of pharmaceutical economics and policy.

Course Functioning: Each week we will meet for approximately two hours and discuss the required readings. These readings usually will consist of journal articles, government reports and/or book chapters relating to a specific topic. We have attempted to limit the readings each week so that you will be more likely to complete the readings and take more time in doing so. This approach, however, sacrifices a more complete understanding of the topics. Although we have attempted to choose readings that are representative, often, there is more that could be done.

Attendance, adequate preparation, and participation in class discussions are required if you want to receive full credit in the course. Some of the material we cover in class is not in the assigned readings, while some material is sufficiently covered. Therefore, class time will be used to expand and discuss materials in the readings, not simply to restate it. If you are unable to attend a class meeting, please discuss this with the course director and make arrangements to assure adequate coverage of the learning objectives.

We will not lecture in this course. Instead, one of us, students, faculty, and/or guests, will lead the discussion each week. The Instructors will act as facilitators and attempt to answer questions and clarify points in the readings. During weeks in which no one is assigned to lead the discussion, we will discuss the readings as a group.

Grading: Your grade will be based on the following criteria:

1. Class attendance and participation: **10 points**

You are expected to read assigned materials prior to class; assessment of attendance and participation will be based on whether you have prepared sufficiently to participate in class discussions. Although you may be excused from class if a valid reason is presented to the course director prior to the start of class, excessive absences may affect the final grade assigned.

2. Leading the class discussion once: **15 points**

Each student will be expected to present assigned readings related to a topic area presented during the semester. Presentation schedules will be assigned during the first week of class. Presentations should be based on the assigned reading(s). Students will be asked to summarize the readings assigned to them and lead in class discussion to facilitate an exchange of ideas surrounding the article topic presented. The method of presentation (e.g., Powerpoint, handout, example, etc) is to be selected by the individual presenter. The delivery of content is important. It is expected that each student engage the class in active discussion and not simply lecture on content. A grading rubric for this assignment is included in Moodle and you are encourage to review the rubric to see exactly what criteria you will be graded on so that you include these criteria in your discussion.

3. Reflection papers **25 points**

Students will be given a series of 6 short written assignments to complete during the course of the semester related to topics being discussed. Each assignment will have 5 points and the lowest grade received on a written assignment will be thrown out for a final cumulative total of 25 points.

4. Pharmaceutical Policy Commentary Paper **50 points**

A grading rubric is posted on Moodle. Students are expected to select a relevant policy issue of interest to them. This could be a topic discussed in class or another topic of interest which was not covered, but related to pharmaceutical policy. Prepare a commentary of this topic for submission to a journal of your choice. A number of points should be included in the commentary as outlined in the grading rubric posted on Moodle. Each commentary should include a presentation of the effectiveness of the policy and potential limitations of the policy. The commentary should include an extensive review of the literature on the selected topic and the strength of evidence about the policy and its effect on at least one stakeholder of interest. Attention should also be paid to the gaps in the literature. References should be included in each paper. The papers should be written independently and must be between 8 and 10 pages in length (double-spaced, 12 point font) excluding references. Papers should be formatted for journal submission as a commentary and must include the following information:

1) A cover page with title and student name and affiliation
2) A structured abstract no longer than 300 words in length
3) The primary text of the paper (8-10 pages in length)
4) A structured reference section.

The cover page, abstract, and references will not be counted toward the 8-10 page length requirement. Papers will be evaluated on content, clarity, and originality. A description of the topic and a brief 1-2 page outline of the paper will be due in class on October 9th. The final paper is due in class on December 4th. Examples of prior commentaries derived from this a similar course which have been published in relevant medical journals are available on Moodle as reference

Grading Scale: This course will use the standard University approved grading scale, A-F.

A	100 – 92
A-	91 – 90
B+	89 – 88
B	87 – 82
B-	81 –80
C+	79 – 78
C	77 – 72
C-	71 – 70
D	69 – 60
F	59 and below

A -- achievement that is outstanding relative to the level necessary to meet course requirements.

B -- achievement that is significantly above the level necessary to meet course requirements.

C -- achievement that meets the course requirements in every respect.

D -- achievement that is worthy of credit even though it fails to meet fully the course requirements.

S -- achievement that is satisfactory, which is equivalent to a C- or better (achievement required for an S is at the discretion of the instructor but may be no lower than a C-).

F (or N) -- Represents failure (or no credit) and signifies that the work was either (1) completed but at a level of achievement that is not worthy of credit or (2) was not completed and there was no agreement between the instructor and the student that the student would be awarded an I (Incomplete).

Policy on Incomplete Coursework

Incomplete coursework is a major inconvenience for students and instructors. We expect you to do everything in your power to avoid this situation. Legitimate excuses include verified illnesses and family emergencies (serious illnesses and funerals). No incompletes will be given unless you have a prior written agreement with one of the instructors.

If an illness, family emergency or other extreme situation arises, we will discuss the circumstances and agree on an appropriate timeline for completion of any work. We will both sign an agreement that specifies what work needs to be completed and by what date. **If the work is not completed by that point, your incomplete will be changed to and 'F' for the course.**

Plagiarism Policy

Academic integrity is essential to a positive teaching and learning environment. All students enrolled in University courses are expected to complete coursework responsibilities with fairness and honesty. Failure to do so by seeking unfair advantage over others or misrepresenting someone else's work as your own can result in disciplinary action. The University Student Conduct Code defines scholastic dishonesty as follows:

> **Scholastic Dishonesty:** Scholastic dishonesty means plagiarizing; cheating on assignments or examinations; engaging in unauthorized collaboration on academic work; taking, acquiring, or using test materials without faculty permission; submitting false or incomplete records of academic achievement; acting alone or in cooperation with another to falsify records or to obtain dishonestly grades, honors, awards, or professional endorsement; altering forging, or misusing a University academic record; or fabricating or falsifying data, research procedures, or data analysis.

Within this course, a student responsible for scholastic dishonesty can be assigned a penalty up to and including an "F" or "N" for the course. **If you have any questions regarding the expectations for a specific assignment or exam, ASK!!**

Class Schedule with Readings

9/3/2019	**Week 1: An Overview of the U.S. Health Care System and Pharmaceutical Spending**
	Learning Objectives 1. Introduction to the class 2. Discuss the role of government regulation in the health care sector 3. Compare and contrast the pharmaceutical market to other health care sectors 4. Discuss the state of the current pharmaceutical market
	Required Readings 1. Martin AB, Hartman M, Washington B, et al (2019) National Health Care Spending In 2017: Growth Slows To Post–Great Recession Rates; Share Of GDP Stabilizes. *Health Affairs.* 38(1): 96-106. 2. Sisko AM, Keehan SP, Poisal JA et al. (2019) National health expenditure projections, 2018-2027: Economic and demographic trends drive spending and enrollment growth. *Health Affairs.* 38(3) 491-501. 3. Schumock GT, Stubbings J, Wiest MD et al. (2019) National trends in prescription drug expenditures and projections for 2018. *American Journal of Health-System Pharmacy*. 76(15):1105-1120. 4. Kesselheim AS, Avorn J, Sarpatwari A (2016) The high cost of prescription drugs in the United States: Origins and prospects for reform. *JAMA*. 316(8):858-871
	Suggested Readings 1. Cutler D (2018) What is the US health spending problem? *Health Affairs*. 493-497. 2. Dieleman JL, Squires E, Bui AL et al. (2017) Factors associated with increases in US health care spending, 2996-2013. *JAMA* 318(17): 1668-1678.
9/10/2019	**Week 2: Informing Policy: The Role of Agenda Setting and Critical Evaluation of Evidence**
	Learning Objectives 1. Describe the role of scientific evidence in pharmaceutical policy making 2. Describe the importance and process of agenda setting in policy making 3. Understand the threats to validity and strength of evidence associated with different study designs when evaluating pharmaceutical policy research studies
	Required Readings 1. Majumdar SR, Soumerai SB. (2009) The unhealthy state of health policy research. *Health Affairs*. 28(5): w900-w908. 2. Harris AD, McGregor JC, Perencevich EN et al. (2006) The use and interpretation of quasi-experimental studies in medical informatics. *Journal of the American Medical Informatics Association*. 13:16-23. 3. Cobb RW, Elder CD. (1971) The politics of agenda-building: An alternate perspective for modern democratic theory. *The Journal of Politics*. 33:892-915. 4. Borchers AT, Hagie F, Keen CL, Gershwin MR. (2007) The history and contemporary challenges of the US Food and Drug Administration. *Clinical Therapeutics* 2007; 29(1):1-16.
	Suggested Readings

	1. Smith GC, Pell JP. (2003) Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomized controlled trials. *British Medical Journal.* 327:1459-1461.
9/17/2019	**Week 3: Pharmaceutical Regulation in the U.S. Health Care System**
	Learning Objectives 1. Discuss the origins and evolution of US pharmaceutical policy and the FDA 2. Review the standard regulatory approval process for new medications 3. Discuss limitations in the current drug approval process 4. Understand the categories of drug approval and requirements for approval
	Required Readings 1. Kesselheim AS and Darrow JJ. (2015) FDA designations for therapeutics and their impact on drug development and regulatory review outcomes. *Clinical Pharmacology & Therapeutics* 97(1):29-36. 2. Darrow JJ, Avorn J, Kesselheim AS (2018) The FDA breakthrough-drug designation – Four years of experience. *NEJM* 378(15):1444-1453. 3. Darrow JJ, Avorn J, Kesselheim AS. (2017) Speed, safety, and industry funding – From PDUFA I to PDUFA VI. *NEJM* 377(23): 2278-2286. 4. Gassman AL, Nguyen CP, Joffe HV (2017) FDA regulation of prescription drugs. *NEJM*. 376(7):674-682
	Suggested Readings 1. Chambers JD, Thorat T, Wilkinson CL, Neuman PJ. (2017) Drugs cleared through the FDA's expedited review offer greater gains than drugs approved by conventional process. *Health Affairs.* 36(8): 1408-1415.
9/24/2019	**Week 4: Post-Marketing Regulation of Pharmaceutical Products**
	Learning Objectives 1. Discuss limitations in the drug development process and implications for safety 2. Discuss limitations in the regulatory approval process for medications 3. Describe FDA directives to monitor post-marketing safety surveillance 4. Understand the differential risk of safety concerns by approval status of drugs
	Required Readings 1. Downing NS, Shah ND, Aminawung JA et al. (2017) Postmarket safety events among novel therapeutics approved by the US Food and Drug Administration between 2001-2010. *JAMA.* 317(18):1854-1863. 2. Puthumana J, Wallach JD, Ross JS (2018) Clinical trial evidence supporting FDA approval of drugs granted breakthrough therapy designation. *JAMA.* 320(3):301-303. 3. Wu J, Juhaeri J. (2016) The US Food and Drug Administration's Risk Evaluation and Mitigation Strategy (REMS) program – Current status and future direction. *Clinical Therapeutics.* 38(12):2526-2532. 4. Woloshin S, Schwartz LM, White B, Moore TJ. (2017) The fate of FDA post-approval studies. NEJM. 377(12):1114-1117. 5. Carpenter D, Zucker EJ, Avorn J. (2008) Drug-review deadlines and safety problems. *New England Journal of Medicine*. 358(13)1354-61.
	Suggested Readings 1. Frank C et al (2014) Era of faster FDA drug approval has also seen increased black box warnings and market withdrawals. *Health Affairs*. 33(8):1453-1459.

	2. Government Accountability Office (2015) FDA expedites many applications, but data for post-approval oversight need improvement. https://www.gao.gov/products/GAO-16-192 3. Bateman-House A, Robertson CT (2018) The federal right to try act of 2017- A wrong turn for access to investigational drugs and the path forward. *JAMA Internal Medicine*. 178(3):321-322.
10/1/2019	**Week 5: Prescription Drug Development and the Pharmaceutical Industry**
	Learning Objectives 1. Provide an overview of the pharmaceutical and biotechnology industries 2. Review estimates of the cost of developing new medications 3. Describe dilemmas between innovation and access for medications 4. Review research and development trends in the pharmaceutical industry 5. Describe failures in the pharmaceutical industry market
	Required Readings 1. DiMasi JA, Grabowski HG, Hansen RW. (2016) Innovation in the pharmaceutical industry: new estimates of R&D costs. *J Health Economics*. 47(1):20-33 2. Schuhmacher A, Grassman O, Hinder M. (2016) Changing R&D models in research-based pharmaceutical companies. *Journal of Translational Medicine.* 14(105):1-11. 3. Goldsmith AD, Varela FE. (2017) Fragmentation in the biopharmaceutical industry. *Drug Discovery Today*. 22(2): 433-439. 4. Berndt ER et al. (2015) Decline in economic returns from new drugs raises questions about sustaining innovations. *Health Affairs.* 34(2):245-252.
	Suggested Readings 1. Khanna I (2012) Drug discovery in pharmaceutical industry: productivity challenges and trends. Drug Discovery Today. 17(19/20):1088-1102. 2. Cleary EG, Bierlein JM, Khanuja NS (2018) Contribution of NIH funding to new drug approvals 2010-2016. https://www.pnas.org/content/pnas/115/10/2329.full.pdf 3. Light DW, Lexchin JR (2012) Pharmaceutical research and development: what do we get for all that money? *BMJ*. 344 https://www.bmj.com/content/345/bmj.e4348
10/8/2019	**Week 6: Generic Medication Approval, Pharmaceutical Patents, and Market Exclusivity**
	Learning Objectives 1. Discuss the Abbreviated New Drug Process 2. Describe the Drug Price Competition and Patent Term Restoration (Hatch-Waxman Act) of 1984 and other market exclusivity provisions 3. Discuss the balance between incentives for innovation and the need for affordability 4. Discuss the role of generics on pharmaceutical pricing and competition
	Required Readings 1. Wang B, Liu J, Kesselheim AS. (2015) Variations in time of market exclusivity among top-selling prescription drugs in the United States. *JAMA Internal Medicine.* 175(4):635-637. 2. Gupta R, Kesselheim AS, Downing N, Greene J, Ross JS. (2016) Generic drug approvals since the 1984 Hatch-Waxman Act. *JAMA Internal Medicine*. 176(9):1391-1393 http://archinte.jamanetwork.com/article.aspx?articleid=2534150

	3. Kesselheim AS, Sinha MS, Avorn J. (2017) Determinants of market exclusivity for prescription drugs in the U.S. *JAMA Internal Medicine.* 177(11):1658-1664. 4. Stevenson JG, Popovian R, Jacobs I, Hurst S, Shane LG. (2017) Biosimilars: Practical considerations for pharmacists. *Annals of Pharmacotherapy.* 51(7):590-602. 5. Baker DE. (2017) For sale: FDA priority review vouchers. *Hospital Pharmacy.* 52(5):324-325. 6. Jain N, Hwang T, Franklin JM, Kesselheim AS. (2017) Association of the priority review voucher with neglected tropical disease drug and vaccine development. *JAMA.* 318(4):388-389. 7. Cote A, Keating B (2012) What is wrong with orphan drug policies? *Value in Health.* 15: 1185-1191.
	Suggested Readings 1. Grabowski H, Long G, Mortimer R, Boyo A. (2016) Updated trends in US brand-name and generic drug-competition. *J Med Economics*. 1-9 2. Gagnon MA, Volesky KD (2017) Merger mania: mergers and acquisitions in the generic drug sector from 1995-2016. *Globalization and Health.* 13(62): https://doi.org/10.1186/s12992-017-0285-x 3. Grabowski HG, Vernon JM. (1992) Brand loyalty, entry, and price competition in pharmaceuticals after the 1984 drug act. *Journal of Law and Economics*. 35:331-350. 4. Kesselheim AS. (2010) Using market-exclusivity incentives to promote pharmaceutical innovation. *NEJM*. 363(19): 1855-1862. 5. Sarpatwari A, Kesselheim AS. (2019) Reforming the orphan drug act for the 21st century. *New England Journal of Medicine.* 381(2):106-108.
10/15/2019	**Week 7: Limitations in the Generic Pharmaceutical Market**
	Learning Objectives 1. Describe industry strategies to limit or delay competition to generic medications 2. Describe the follow-on biologic process and limitations 3. Describe the impact and potential solutions to drug shortages in the marketplace 4. Review proposals to improve generic pharmaceutical approval and marketing
	Required Readings 1. Vokinger KN, Kesselheim AS, Avorn J, Sarpatwari. (2017) Strategies that delay market entry of generic drugs. *JAMA Internal Medicine.* 177(11):1665-1669. 2. Feldman R, Wang C. (2017) A citizen's pathway gone astray – Delaying competition from generic drugs. *NEJM* 376(16):1499-1501. 3. Downing NS, Ross JS, et al. (2012) Avoidance of generic competition by Abbott Laboratories' fenofibrate franchise. *Archives of Internal Medicine.* 172(9):724-730. 4. Dave CV, Kesselheim AS, Fox E et al. (2017) High generic drug prices and market competition. *Annals of Internal Medicine.* 167:145-151. 5. Yang YT, Chen B, Bennett CL. (2017) Biosimilars – Curb your enthusiasm. *JAMA Oncology.* 3(11):1467-1468. 6. Hakim A, Ross JS. (2017) Obstacles to the adoption of biosimilars for chronic diseases. *JAMA.* 317(21):2163-2164. 7. Frank RG (2018) Friction in the path to use of biosimilar drugs. *NEJM*. 791-793. 8. Cole AL, Dusetzina SB (2018) Generic price competition for specialty drugs: Too little, too late? *Health Affairs*. 37(5):738-742.
	Suggested Readings

	1. Kesselheim AS, Murtagh L, Mello MM. (2011) "Pay for Delay": Settlements of disputes over pharmaceutical patents. *NEJM*. 365(15):1439-1445. 2. Outterson K, Powers JH, Daniel GW, McClellan MB (2015) Repairing the broken market for antibiotic innovation. *Health Affairs*. 34(2)277-285
10/22/2019	**Week 8: Pharmaceutical Pricing**
	Learning Objectives 1. Review US drug prices in relation to international drug prices 2. Understand common price references (AWP, WAC) for pharmaceuticals in the U.S. 3. Examine the role of rebates on pharmaceutical prices 4. Examine the role of pharmacy benefit managers on pharmaceutical prices
	Required Readings 1. Dabora MT, Turaga N, Schulman KA (2017) Financing and distribution of pharmaceuticals in the United States. *JAMA*. 318(1):21-22. 2. Dusetzina SB, Conti RM, Lu NL, Bach PB. (2017) Association of prescription drug price rebates in Medicare Part D with patient out-of-pocket and federal spending. *JAMA Internal Medicine.* 177(8):1185-1188. 3. Schulman KA, Richman BD (2018) The evolving pharmaceutical benefits market. *JAMA.* 319(22):2269-2270. 4. Schondelmeyer SW, Purvis L. (2017) Trends in retail prices of specialty prescription drugs widely used by older Americans, 2006-2015. AARP Public Policy Institute. https://www.aarp.org/content/dam/aarp/ppi/2017/11/full-report-trends-in-retail-prices-of-specialty-prescription-drugs-widely-used-by-older-americans.pdf
	Suggested Readings 1. Schweitzer SO, Comanor WS. (2011) Prices of pharmaceuticals in poor countries are much lower than in wealthy countries. *Health Affairs.* 30(8):1553-1561. 2. Dusetzina SB. (2016) Share of specialty drugs in commercial plans nearly quadrupled, 2003-14. *Health Affairs.* 35(7):1241-1246. 3. Kanavos P, Ferrario A, Vandoros S, Anderson GF. (2013) Higher US branded drug prices and spending compared to other countries may stem partly from quick uptake of new drugs. *Health Affairs.* 32(4):753-760.
10/29/2019	**Week 9: Pharmaceutical Pricing – Proposals for Reform**
	Learning Objectives 1. Describe policy options to improve pharmaceutical pricing in the U.S. 2. Understand the arguments for and against federal management of pharmaceutical pricing 3. Review the merits of recent proposals to manage growth in prescription drug pricing in the U.S.
	Required Readings 1. Egilman AC, Wallach JD, Ross JS, Dhruva SS (2018) Medicare spending and potential savings on brand-name drugs with available generic substitutes excluded by 2 large pharmacy benefit managers, 2012-2015. *JAMA Internal Medicine.*567-569. 2. Schulman KA, Dabora M. (2018) The relationship between pharmacy benefit managers (PBMs) and the cost of therapies in the US pharmaceutical market: A policy primer for clinicians. *American Heart Journal.* 206:113-122.

	3. Dusetzina SB, Bach PB (2019) Prescription drugs – List price, net price, and the rebate caught in the middle. *JAMA*. 321(16):1563-1564. 4. Gellad WF, Ennis M, Kuza CC. (2019) A new safe harbor – turning drug rebates into discounts in Medicare Part D.380(18):1688-1690. 5. Murry L, Gerleman B, Urick B, Urmie J. (2018) Third-party reimbursement for generic prescription drugs: the prevalence of below-cost reimbursement in an environment of maximum allowable cost-based reimbursement. *Journal of the American Pharmacists Association.* 58:421-425. 6. Venker B, Stephenson KB, Gellad WF. (2019) Assessment of spending in Medicare Part D if medication prices from the department of Veterans Affairs were used. *JAMA Internal Medicine.* 179(3):431-433.
	Suggested Readings 1. Outterson K, Kesselheim AS. (2009) How Medicare could get better prices on prescription drugs. *Health Affairs*. Web Exclusive: w832-w841. 2. Joyce GF, Sood NJ (2016) Why Medicare price negotiation is the wrong prescription for rising drug spending. *Journal of Policy Analysis and Management.* 35(4):956-963. https://doi.org/10.1002/pam.21935 3. Conti RM (2016) The advantages of awarding the federal government negotiating power over the prices of prescription drugs. *Journal of Policy Analysis and Management.* 35(4):964-970. https://doi.org/10.1002/pam.21934 4. Department of Health and Human Services. (2018) American Patients First – The Trump administration blueprint to lower drug prices and reduce out-of-pocket costs. https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf
11/5/2019	**Week 10: Federal Coverage of Pharmaceutical Products – Medicare, Medicaid, and the ACA**
	Learning Objectives 1. Describe the different federal programs covering prescription benefits for patients 2. Describe the Medicaid insurance benefit, eligibility and enrollment 3. Describe the Medicare insurance benefit, eligibility and enrollment 4. Discuss limitations and policy proposals to improve federal prescription coverage
	Required Readings 1. Hoadley JF, Cubanski J, Neuman P. (2015) Medicare's Part D drug benefit at 10 years: firmly established but still evolving. *Health Affairs.* 34(10):1682-1687. 2. Trish E, Xu J, Joyce G. (2018) Growing number of unsubsidized Part D beneficiaries with catastrophic spending suggests need for an out-of-pocket cap. *Health Affairs.*37(7):1048-1056 3. Baicker K, Allen HL, Wright BJ, Finkelstein AN. (2017) The effect of Medicaid on medication use among poor adults: Evidence from Oregon. *Health Affairs.* 36(12):2110-2114. 4. Hwang TJ, Jain N, Lauffenburger JC et al. (2019) Analysis of proposed Medicare Part B to Part D shift with associated changes in total spending and patient cost-sharing for prescription drugs. *JAMA Internal Medicine.* 179(3):374-380. 5. Blumenthal D, Abrams M, Nuzum R (2015) The Affordable Care Act at 5 Years. *NEJM*. 372(25):2451-2458.
	Suggested Readings

	1. Li P, McElligott S, Bergquist H, Schwartz S, Doshi JA. (2012) Effect of the Medicare Part D coverage gap on medication use among patients with hypertension and hyperlipidemia. *Annals of Internal Medicine* 156(11): 776-784. 2. Blumenthal D, Davis K, Guterman S (2015) Medicare at 50 – Origins and evolution. *NEJM*. 372(5):479-486. 3. Iglehart JK, Sommers BD. (2015) Medicaid at 50 – From welfare program to nation's largest health insurer. *NEJM*. 372(22):2152-2159. 4. Baicker K, Taubman SL, Allen HL et al. (2013) "The Oregon Experiment – Effects of Medicaid on Clinical Outcomes". *NEJM.* 368(18): 1713-1722. 5. Zhang Y, Donohue JM, Lave JR, O'Donnell G, Newhouse JP. (2009) The effect of Medicare Part D on drug and medical spending. *NEJM.* 361(1):52-61
11/12/2019	**Week 11: Pharmaceutical Managed Care Strategies**
	Learning Objectives 1. Describe the use of demand side controls to curb pharmaceutical spending (e.g. copayments and deductible) 2. Describe the use of supply side controls available to curb pharmaceutical utilization and spending (e.g. prior authorizations, quantity limits, & formularies) 3. Understand the effectiveness and unintended consequences from applying managed care policies to pharmaceuticals
	Required Readings 1. Chambers JD, Kim DD, Graf JS et al. (2018) Specialty drug coverage varies across commercial health plans in the U.S. *Health Affairs.* 37(7):1041-1047. 2. Goldman DP, Joyce GF, Escarce JJ et al. (2004) Pharmacy benefits and the use of drugs by the chronically ill. *JAMA*. 291(19):2344-2350. 3. Maciejewski ML, Wansink D, Lindquist JH, Parker JC, Farley JF. (2014) Value-based insurance design program in North Carolina increased medication adherence but was not cost neutral. *Health Affairs.* 33(2): 300-308. 4. Happe LE, Clark D, Holliday E, Young T. (2014) A systematic literature review assessing the directional impact of managed care formulary restrictions on medication adherence, clinical outcomes, economic outcomes, and health care resource utilization. *J Manag Care Pharm*. 20(7):677-684.
	Suggested Readings 1. Soumerai SB, et al. (1994) Effects of limiting Medicaid drug reimbursement benefits on the use of psychotropic agents and acute mental health services by patients with schizophrenia. *New England Journal of Medicine*. 331(10):650-655. 2. Li P, McElligott S, Bergquist H, Schwartz S, Doshi JA. (2012) Effect of the Medicare Part D coverage gap on medication use among patients with hypertension and hyperlipidemia. *Annals of Internal Medicine* 156(11): 776-784. 3. Gleason PP, Starner CI, Gunderson BW et al. (2014) Association of prescription abandonment with cost share for high-cost specialty pharmacy medications. *Journal of Managed Care Pharmacy*. 15(8):648-658.
11/19/2019	**Week 12: Pharmaceutical Policies: International Variations**
	Learning Objectives 1. Compare and contrast pharmaceutical policies from other countries to the U.S. 2. Explore the evidence of effectiveness of international pharmaceutical policies

	3. Understand how cost-effectiveness analysis is applied to pharmaceutical coverage decisions in other countries
	Required Readings 1. Schneeweiss S. et al. (2002) Outcomes of reference pricing for angiotensin-converting-enzyme inhibitors. *New England Journal of Medicine*. 346(11):822-829. 2. Sood N, et al. (2008) The effect of regulation on pharmaceutical revenues: experience in nineteen countries. *Health Affairs*. W125-W137. 3. Clement FM, Harris A, Li HH, Yong K, Lee KM, Manns BJ. (2009) Using effectiveness and cost-effectiveness to make drug coverage decisions: A comparison of Britain, Australia, and Canada. *JAMA*. 302(13):1437-1443. 4. Persson U, Jonsson B. (2016) The end of the international reference pricing system? *Applied Health Economics and Health Policy*. 14(1):1-8. 5. Gupta R, Bollyky TJ, Cohen M et al. (2018) Affordability and availability of off-patent drugs in the United States – the case for importing from abroad: observational study. *BMJ*. https://www.bmj.com/content/bmj/360/bmj.k831.full.pdf
	Suggested Readings 1. Leopold C, Vogler S, Mantel-Teeuwisee AK, et al. (2012) Differences in external reference pricing in Europe – A descriptive review. *Health Policy.* 104:50-60. 2. Kantarjian H, Mathisen MS (2015) Having "skin in the game" and allowing cross-border importation of drugs to lower high prices of cancer drugs. *JAMA Oncology.* 1(6):729-730.
11/26/2019	**Week 13: Pharmaceutical Promotion**
	Learning Objectives 1. Understand the pro and con arguments for promoting pharmaceuticals 2. Describe the spending and types of promotion for pharmaceuticals employed by manufacturers 3. Provide an overview of the regulation for promotion of pharmaceuticals 4. Describe the different types of promotion directed to providers and patients
	Required Readings 1. Hartung D, Johnston K, Cohen D et al. (2018) Industry payments to physician specialists who prescribe repository corticotropin. *JAMA Network Open.* 1(2)e180482. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2686039 2. Dusetzina SB, Mello MM. (2018) Disclosing prescription drug prices in advertisements – legal and public health issues. *New England Journal of Medicine.* 379(24):2290-2293 3. Applequist J, Ball JG. (2018) An updated analysis of direct-to-consumer television advertisements for prescription drugs. *Annals of Family Medicine.* 16(3):211-216. 4. Larkin I, Steinhart J, Chao M et al. (2017) Association between academic medical center pharmaceutical detailing policies and physician prescribing. *JAMA.* 317(17):1785-1795. 5. Schwartz LM, Woloshin S. (2019) Medical marketing in the United States, 1997-2016. *JAMA.* 321(1). 80-96.
	Suggested Readings 1. Kim H. (2015) Trouble spots in online direct-to-consumer prescription drug promotion: a content analysis of FDA warning letters. *International Journal of Health Policy and Management*. 4(12):813-821

	2. Robertson C, Kesselheim AS (2016) Regulating off-label promotion – A critical test. *NEJM*. 2313-2315. 3. DeJong C, Aguilar T, Tseng CW et al. (2016) Pharmaceutical industry-sponsored meals and physician prescribing patterns for Medicare beneficiaries. *JAMA Internal Medicine* 176(18):1114-1122. 4. Sullivan HW, Aikin K, Chung-Davies E, Wade M. (2016) Prescription drug promotion from 2001-2014: Data from the U.S. Food and Drug Administration. *PLoS One*. 11(5): https://doi.org/10.1371/journal.pone.0155035 5. Kesselheim AS, Mello MM, Studdert DM (2011) Strategies and practices in off-label marketing of pharmaceuticals: A retrospective analysis of whistleblower complaints. *PLoS Med*. 8(4):e1000431: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3071370/
12/3/2019	**Week 14: The Shift from Volume to Value in Health Care**
	Learning Objectives 1. Describe the process of outcomes-based contracting for pharmaceuticals 2. Describe the process of pay-for-performance for health care services 3. Understand the types of performance measurements available to measure value 4. Understand the evidence of effectiveness for using value to pay for health care
	Required Readings 1. Duhig AM, Saha S, Smith S, Kaufman S, Hughes J (2018) The current status of outcomes-based contracting for manufacturers and payers: An AMCP Membership Survey. *J Manag Care Spec Pharm.* 24(5):410-415. 2. Benner J, Bick M, Brill JV et al. (2017) AMCP partnership forum: advancing value-based contracting. *J Manag Care Spec Pharm.* 23(11)1096-1102. 3. Findley S, Berencon R, Lott R, Richardson M. (2017) Implementing MACRA. Physicians who treat Medicare beneficiaries are subject to a new law and regulations governing their payment. *Health Affairs Health Policy Brief.* https://www.healthaffairs.org/do/10.1377/hpb20170327.272560/full/healthpolicybrief_166.pdf 4. Campbell JD, Belozeroff V, Whittington MD et al. (2018) Prices for common cardiovascular drugs in the US are not consistently aligned with value. *Health Affairs*. 37(8): 1298-1305. 5. Owen JA. (2014) Medicare star ratings: stakeholder proceedings on community pharmacy and managed care partnerships in quality. *JAPhA. 54:228-240.*
	Suggested Readings 1. Roberts ET, Zaslavsky AM, McWilliams M (2018) The value-based payment modifier: program outcomes and implications for disparities. *Annals of Internal Medicine.* 168(4):255-265. 3. Fox J, Watrous M. (2017) Overcoming challenges of outcomes-based contracting for pharmaceuticals: Early lessons from the Genentech-Priority Health Pilot. *Health Affairs Blog.* https://www.healthaffairs.org/do/10.1377/hblog20170403.059442/full/
12/10/2019	**Week 15: Stump the Professor**