

Medicare D as a Teaching Opportunity:
Lessons in Health Policy and Quality Prescribing

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Summary:

The recent introduction of Medicare D has presented a myriad of problems for patients, physicians, and pharmacists. However, it also offers an ideal opportunity to teach about “real world” systems based practice by exemplifying both construction of health policy at a national level, the design and utilization of formularies and the responsibility of physicians to prescribe based on available evidence. Through the use of small group discussion of case studies pulled from the Medicare D experience, this workshop will offer participants a brief overview of formulary construction, national standards for formulary guidelines, and the concept of “healthy” or quality prescribing. The philosophical, political, and medical underpinnings of Medicare D, will be utilized to demonstrate the extent to which this experience can offer multiple teaching opportunities on aspects of health policy, pharmaceutical policy, and clinical medicine. Participants will generate teaching ideas to transform complaints about rules and control into opportunities to learn about topics often marginalized in graduate medical curricula. Examples include directing residents to unbiased drug information, utilization of national or specialty treatment guidelines, and consideration of the underpinnings of formularies. Likewise, participants will gain an appreciation for how the lessons of Medicare D can be used to transform physician feelings of powerlessness and frustration into valuable opportunities for physician advocacy. This is not a workshop on Medicare D itself.

Educational Objectives:

Participants will be able to:

- 1) Explore the rationale for formularies, define principles on which to base an ideal national prescription drug benefit, and analyze Medicare D by these standards.
- 2) Describe the principles of healthy (quality) prescribing and recommend sources for unbiased pharmaceutical information.
- 3) Identify the challenges to healthy (quality) prescribing presented by multiple formularies.
- 4) List opportunities presented by Medicare D to involve physicians in individual and systemic advocacy.

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SGIM Annual Meeting Workshop WF05 April 2007

CASE I: Prescription benefits and health policy

The year is anytime before 2003. You have won a one year fellowship to work as a health policy advisor to your Congressman or Senator. He or she asks for your help in constructing a pharmacy benefit for Medicare. You are naïve about the political process but feel fairly secure in your knowledge about what your patients need, and the kinds of pharmaceutical access problems they have had. What do you need to consider as you prepare a position paper for your legislator?

CASE II: Healthy Prescribing

One of the clinic residents is presenting a patient with hypertension, diabetes, hyperlipidemia, arthritis, urinary incontinence, and osteoporosis. The resident reminds you that her patient has not been able to adhere to her regimen, partly because she cannot afford her medications. She is on Toprol XL from a cardiologist, metformin, lisinopril, Lipitor, Fosamax, and Relafen. She takes occasional Fioricet for migraine headaches. The gynecologist just gave her samples and a prescription for a new medicine for incontinence. She has just turned 65 and is eligible for the Medicare drug benefit, and you hope this will help. You and the resident return together to see the patient.

What teaching opportunities regarding prescribing and prescription drugs does this case provide? What structural/organizational changes could you implement in residents clinic to teach healthy prescribing?

Case III: Advocating for Patients

Scenario #1: Mr. Walker, a patient with alcoholism, comes to clinic and reports that his chronic dyspepsia is better because he is going to AA and has been sober for 3 weeks. The resident wants to give him a prescription for the new medication Campral (acamprosate) after hearing about it at a recent noon conference. After checking first, he notes it is not on Mr. Walker's Medicare plan formulary. . The resident feels well informed about the medication, and thinks it offers his patient the best chance for ongoing sobriety. The resident asks you how he can get Mr. Walker the medication.

Scenario #2: A resident asks your advice. She has a patient who has a long list of medication allergies and intolerances. She has finally gotten her cholesterol at target on Lipitor, which was on the formulary of the Medicare drug plan she chose. However, six months into the plan, she has received notice that Lipitor is being moved to a Tier 3 medication with higher co-pay. You nod wisely, remembering that simvastatin (Zocor) has just become generically available and you realize that the plan now wants to move people to a generic drug. However, the resident feels quite certain that her patient will develop a side effect to any new generic drug, and that she will not be able to afford the higher price of a Tier 3 medication. She asks your advice.

How would you help residents decide whether it is appropriate to ask for prior authorization for either a non-formulary medication, or one that requires prior authorization? If you decide it is appropriate, what resources and skills do we need to do this advocacy?

Ten Ideas for Teaching About Prescribing and Formularies

1. Bookmark frequently used formularies on teaching room computers; be sure each resident who uses a PDA downloads formularies.
2. Maintain a library of unbiased sources of drug information: identify it and publicize it. Bookmark electronic sites and identify them collectively as unbiased sources of drug information.
3. Reframe a problem: Move from “the drug isn’t on the formulary” to “how would you choose a drug for that condition?”
4. Always ask if there is a non-drug approach to the problem
5. Ask a resident to list the benefits and drawbacks of formularies.
6. Ask a resident to name two adverse effects of any drug they are choosing to prescribe.
7. Raise the issue of costs: co-payment, co-insurance; retail costs. How easy is it to consider cost when prescribing? How would the resident approach the problem of cost controls for pharmaceuticals?
8. Ask a resident to consider why the drug he/she wished to prescribe might not be on a formulary, or why they think it should be on a formulary.
9. Ask a resident to consider why a pharmacy plan might require prior authorization for the medication in question. Discuss the relative influences of cost, pharmaceutical marketing, national guidelines, off-label uses, or other quality issues.
10. Discuss the role of physician as advocate, including the difference between physician and social worker advocacy, and the use of outside help (lawyers) in obtaining medications or services for patients.

Principles for Careful/Judicious/Safe/Effective Prescribing

1. Seek and exhaust non-drug alternatives as a first rather than as a last resort; including exercise, physical therapy, lifestyle changes, counseling, diet changes, even surgery (e.g., drain the abscess).
2. Focus on prevention rather than just treating symptoms. Even for drugs that “work” be wary of just treating end stage manifestations or marginal impact. Prevention often provides greater “upstream” bang-for-buck, more effective in the long run.
3. Consider underlying causes of the problems rather than just treating the manifestations with a drug: could elevated cholesterol be hypothyroidism? Impotence, marital discord? Arthritis pain, osteomalacia or work-induced trauma?
4. Use only a few drugs and learn to use them well; become familiar with a limited number of drugs.
5. Get colleagues on the same page as you so you are all using the same small set of familiar drugs. Then, when you cross-cover or care for the same patients, you can take advantage of this familiarity and standardization, drawing on a limited collective/shared formulary.
6. Avoid “impulse switching”—frequent switching between drugs without clear compelling evidence-based reasons.
7. Use the “test of time” as a diagnostic (and therapeutic) trial wherever possible when dealing with self-limiting conditions or variable symptoms rather than reaching for a drug which can often just confuse the picture. Reassurance and an open door (if patient not getting better on her own) can often be as effective as a drug. In many cases, you can always start the drug later.
8. Be skeptical about “individualizing” therapy—it often involves chasing random variation in patients’ symptoms/course.
9. Be reluctant to prescribe “over the phone” (e.g., antibiotics). Take time to see and examine the patient whenever possible. Allow enough time for the patient talk to fully hear and find out what's really going on.
10. Have high index of suspicion for adverse drug effects (e.g., leg pain that isn't arthritis but statin-induced rhabdomyolysis).
11. Be careful that you're not treating withdrawal symptoms from a drug (e.g., person has become dependent on that drug or is abusing drugs, chronic daily headache often due to drug or drug withdrawal, insomnia due to benzodiazepine or alcohol withdrawal). (see Medicines Out of Control –book; www.socialaudit.org.uk/)
12. Seven-year rule (Lasser, JAMA 2002; www.worstpills.org): Do not be the first on your block to use a new drug. Recognize how prescribing fads come and go. New drugs always *appear to be* safer only because not enough time has passed or not enough patients have been exposed to allow rarer adverse effects to be identified.

13. Learn about drugs from credible, unbiased, sources (i.e. peer reviewed journals, although even these not always sufficiently independent), other print and web references, drug information bulletins, colleagues with reputation for integrity and conservative use of drugs. Evaluate claims for new drugs claims skeptically, rely/insist on high quality studies.
14. Be careful and concerned about “indication creep”—often very narrow type of patient selected for pre-marketing trials. Those are only ones proven to benefit.
15. Don't be seduced by fancy physiology and technology (e.g., neat pharmacologic mechanism of action but little or no clinical outcomes data to justify this promise).
16. Beware of catchy study titles (e.g., VIGOR, IMPROVE trials). They are seductively easy to remember, and may be misleading and lead to overuse of otherwise non-optimal drugs.
17. Do not have a knee-jerk response to patient requests for drugs, especially drugs they have heard advertised.
18. Be familiar with/anticipate/look out for/search out/monitor for adverse drug reactions. Take patients complaints of what they say are drug-induced symptoms seriously, no matter how “weird”—that they might be adverse drug reactions.
19. Educate patients about possible adverse drug reactions in advance so that: a) you won't miss them, b) they are more likely to be recognized early, c) you will appreciate and weigh in decision making discussions up front (e.g., “oh, I didn't realize that drug could cause bleeding, I don't think I want the prescription”), d) you can contribute to reporting and better understanding of recognized and previously unrecognized ADRs.
20. Be attentive to the environmental systems changes that may make drug therapy safer (e.g., high-quality computerized prescriber order entry (CPOE)).
21. Avoid (either knowingly or unknowingly because you lack good/complete drug history) repeat trials of a drug that a person has tried and failed or had an adverse reaction to in the past.
22. Be cognizant/attentive to patient self-regulation of drug therapy (eg nonadherence)—don't erroneously treat it by increasing the dose or adding new drugs for “suboptimal response.”
23. Consider broader impacts of using drugs (e.g., extensive antibiotic use leading to increased drug resistance, accumulation of antibiotics or toxic chemicals in the water supply).
24. For a given patient, use as few drugs as possible and discontinue as many drugs as possible, as often as possible.

Resources on Healthy Prescribing, formularies, and related health policy

This annotated list includes sources for additional information about Medicare, formularies, pharmaceutical policy, and drug information. It also includes advocacy resources, and information for beneficiaries. In general, this list does not include articles easily searched on Medline. Instead, it is meant to suggest other sources for information on these topics. It is more eclectic than exhaustive, suggestive of the many avenues for teaching and learning that Medicare D, formularies, and prescribing present to us.

Health Policy:

The following websites or journals are excellent general places to start when looking for information on health policy: They have a wealth of information and most medical residents are not familiar with them.

The Kaiser Family Foundation

www.kff.org

www.kaiseredu.org

- *This site provides 20 minute power point tutorials, with audio, on basic health policy subjects. It includes one called Medicare 101 and an updated one on Medicare D, among many others. These are excellent to assign to residents; it is like watching television!*

The Commonwealth Fund

www.cmwf.org

Health Affairs

www.healthaffairs.org

The California Health Care Foundation

www.chcf.org

The National Health Policy Forum

<http://www.nhpf.org/index.htm>

Run out of George Washington University, this organization states prepares policy briefs for Congress and congressional staff. You can go on the site and see what how your freshman congressperson was briefed on Medicaid, Medicare, etc.

Formularies:

Description and analysis of the VA National Formulary. Institute of Medicine 2000. Available at <http://www.nap.edu/books/0309069866/html/>

A useful description of how to look at and analyze both a formulary, and its implementation as a formulary system.

Rucker TD. The HEW Task Force on Prescription Drugs: An Insider's Perspective. The Journal of Research in Pharmaceutical Economics Vol 10 No 2/3 2001.

A fascinating historical look at how long we have been talking about a Medicare drug benefit, and what the issues are. The author was on a task force to design a prescription drug plan for Medicare in 1965. T. Donald Rucker, now retired, has been writing about pharmaceutical health policy for many years. Search Medline for other useful articles by Don Rucker.

Rucker TD, Schiff G. Drug Formularies: Myths-in-formation. Medical Care October 1980 Vol 28 (10).

Another old article before formularies were common, it has a good discussion of physician justifications of irrational prescribing.

Hoadley Jack. The Effect of Formularies and Other Cost Management Tools on Access to Medications: An Analysis of the

MMA and the Final Rule Available at www.kff.org

A practical analysis that demonstrates the importance of the rulemaking process, done by administrative agencies once a law is passed. In this case, CMS rules laid out the rules for formularies that could be offered under Medicare D. Rulemaking is open to public comment and is an important avenue for advocacy.

Hoadley, J. Benefit Design and Formularies of Medicare Drug Plans: A Comparison of 2006 and 2007 Offerings . Available at www.kff.org.

A follow-up to the first article, showing what happened between year 1 and year 2. A good article to read or assign for a teaching conference just on Medicare D or formularies

Landon BE, Reschovsky JD, Blumenthal D. Physicians views of formularies: Implications for Medicare Drug Benefit Design. Health Affairs Jan/Feb 2004 Vol 23 Number 1. *This entire issue of Health Affairs is on the drug industry, and most issues of Health Affairs have at least one article on pharmaceutical policy*

Health Affairs January/February 2004 volume 23 #1

Drug Industry: A Closer Look

Many articles not just on the drug industry, but also on formularies and drug benefit construction. There are a diversity of viewpoints including Uwe Reinhardt and Mark Pauly

Health Affairs March/April 2000 Volume 19#2

Prescription Drugs: What's Next?

For the historical perspective;

Shows what issues have changed; speculates on a Medicare drug benefit

Benefit Design:

Norman Daniels, J. Russell Teagarden, and James E. Sabin

An Ethical Template For Pharmacy Benefits

Health Affairs, January/February 2003; 22(1): 125-137.

Robert F. Atlas. Wrangling Prescription Drug Benefits: A Conversation With Express Scripts'

Barrett Toan

Health Affairs Web Exclusive, April 19, 2005

The American Society for Health System Pharmacists, www.ashp.org has position statements on formulary construction, and formulary systems. <http://www.ashp.org/bestpractices/formulary-mgmt/>, accessible from their site, has guidelines for formulary operations. There is also a statement on the function and organization of a P & T committee, one on Principles of a Sound Formulary System, and a technical assistance bulleting on evaluating drugs for formulary inclusion.

Pharmacy Benefit Managers

The best information on these has appeared in newspapers, including the Wall Street Journal and the New York Times. Milt Freudenheim, of the NYTimes, has written several good pieces over the last few years. The pharmaceutical benefit industry is one of the least transparent industries. Searching it under Google is more useful than Medline.

Geoffrey F. Joyce, PhD; José J. Escarce, MD, PhD; Matthew D. Solomon, MA; Dana P. Goldman, PhD. Employer Drug Benefit Plans and Spending on Prescription Drugs JAMA Vol. 288 No. 14,

October 9, 2002 *Comes to the not surprising conclusions that changes in drug benefit plans save the plans money, but cost the patients more*

Langenfeld, J and Maness, R. The Cost of PBM Self Dealing under a Medicare Drug Benefit. September 2003. Accessible on the web at <http://www.mpaginc.com/news/pbmreport.pdf>

A very long piece on PBMs and the conflict of interest when they function as both benefit managers and mail order pharmaceutical suppliers.

www.pbmi.com The website of the Pharmacy Benefit Management Institute, with a free newsletter that gives you some idea of how the industry is thinking.

Navigating the Pharmacy Benefits Marketplace. Prepared for the California Health Care Foundation by Mercer Human Resource Consulting. Available on the web at <http://www.chcf.org/topics/view.cfm?itemID=20243>

Not about Medicare D as much as employer benefits, but relevant

On managed care and formularies

The Academy of Managed Care Pharmacy www.amcp.org has a journal, available on line, with articles examining various aspects of managed care pharmacy, changing co-pays, etc. As a journal aimed primarily at pharmacists, it presents a different perspective. The journal can be searched by topics, including drug benefit management from the perspective of patient, employer, or pharmacist.

www.aetna.com follow their website to clinical policy bulletins for an inside look at reasoning. Aetna is one of the few commercial plans that publicly lists references for its coverage decisions.

Pharmaceutical policy studies

Soumerai, S. Restricted drug access in Medicaid. Health Affairs Jan/Feb 2004 Vol 23 Number 1.

Choudhry NK, Avorn J, Antman EM, Schneeweiss S, Shrank WH.

Should patients receive secondary prevention medications for free after a myocardial infarction? An economic analysis.

Health Aff (Millwood). 2007 Jan-Feb;26(1):186-94.

And almost any other article by Steve Soumerai or Jerry Avorn, who have looked at pharmaceutical policy in general and Medicaid pharmaceutical policies in particular. Much of this work will be relevant to Medicare formularies

Davis MM, Patel M, Halasyamani LK. Variation in estimated Medicare Prescription Drug Plan costs and affordability for beneficiaries living in different states. JGIM February 2007 22(2): 257-263.

Kaiser Family Foundation website www.kff.org

The website of the Kaiser Family Foundation is a gold mine of health policy information. It also has a separate site, www.kaiserEDU.org, with self-teaching tutorials on Medicare and Medicaid (and other topics) for students/residents. The one on Medicare D has been recently updated. who need Medicare 101.

On pharmaceutical industry and physicians:

www.nofreelunch.org maintains an updated bibliography; there are many good articles on this subject, in the medical literature and the popular press

<http://www.cpsnet.com/Pubs/mmm.asp> is the website of “Medical media and marketing,” a trade publication for the pharmaceutical industry, is full of strategies on reaching physicians with pharma’s message. A good look at how physicians are targeted to affect prescribing habits.

Boston University School of Health. Health Reform Program <http://www.healthreformprogram.org/> has a number of publications analyzing drug company pricing and presents an alternative to the numbers put forth by Pharma.

Recent books on pharmaceuticals, physicians, prescribing influences

Abramson, John. *Overdosed in America: The broken promise of American medicine*. Harper-Collins Books. 2004. *A former primary care doctor discusses the pressures on physicians to prescribe, and the difficulties of interpreting and believing published information on pharmaceuticals and their risks and benefits.*

Angell, Marcia. *The Truth About Drug Companies: How They Deceive Us and What to Do About It*. Random House. 2004. *A former NEJM editor discusses the pharmaceutical industry.*

Avorn, Jerry. *Powerful Medicines. The benefits, risks, and costs of prescription drugs*. Alfred Knopf N.Y. 2004

A long book by an experienced internist and pharmacoepidemiologist who has published many articles on medication use and outcomes. Almost any chapter in the book would make a wonderful article for resident or faculty discussion. An impassioned plea for more effective prescribing, discussing the scientific, economic information technology, quality, and cost issues.

Medical Education on Rational Prescribing

On May 13, 2004, Warner-Lambert, a division of Pfizer, Inc., entered into an Assurance of Voluntary Compliance/Discontinuance with the Attorneys General of 50 States and the District of Columbia to settle allegations that Warner-Lambert conducted an unlawful marketing campaign for the drug Neurontin® that violated state consumer protection laws. Among other things, the settlement provides for a \$21 million Consumer and Prescriber Education grant program. The Attorney General Consumer and Prescriber Education Grant Program will fund programs designed to provide health care professionals and consumers information relating to prescription drugs, including the way in which drugs are marketed. A list of funded projects, including one by Gordy Schiff, MD, a workshop leader in this workshop, is available at <http://www.ohsu.edu/cpgp/fpindex.cfm>

Steinman MA, Bero LA, Chren MM, Landefeld CS. Narrative Review: The promotion of gabapentin. An analysis of internal industry documents. *Ann Intern Med*. 2006 Aug 15;145(4):284-93

Advocacy Organizations working on pharmaceutical issues:

Community Catalyst and the Prescription Access Litigation project www.communitycatalyst.org

National Health Law Project www.healthlaw.org

Pennsylvania Health Law Project www.phlp.org

Public Citizen Health Research Group www.publiccitizen.org/hrg

Center for Medicare Rights www.medicarerights.org

Has a weekly email newsletter, DearMarci, for providers and patients

They have a publication, available on request from their website, on navigating Part D appeals.

"<http://www.medicarerights.org/appealsmanual.html> Medicare Part D Appeals: An advocate's manual to navigating the Medicare private drug plan appeals process."

Families USA www.familiesusa.org

An advocacy organization concerned with access to health care

Center for Medicare Advocacy www.medicareadvocacy.org

Advising for patients: In addition to the above:

<http://www.healthassistancepartnership.org/program-locator/>

This is the website of the state health insurance assistance programs (SHIPS). You can click on a state and get the name and phone number of a state agency trained to help consumers with insurance, and Medicare D questions

<http://www.accesstobenefits.org>

The Access to Benefits Coalition helps beneficiaries determine if they are eligible for the low income subsidy

Many statewide and local legal services organizations

Sources for unbiased information regarding prescription drugs

International Society for Drug Bulletins

<http://66.71.191.169/isdbweb/pag/summary.php>

The Medical Letter www.medicalletter.com

Prescrire and Prescrire International

If your French is good: <http://www.prescrire.org>

If you prefer English: <http://www.prescrire.org/signature/productions/international.php>

A French pharmaceutical bulletin that publishes an international English language edition.

Subscription rates are steep with differential rates depending on the GNP/capita of the country of the subscriber. There are lower student rates.

Prescribers Newsletter

www.therapeuticresearch.net

From their website: *Prescriber's Letter* is a subscription service for prescribers to keep them up to date on new developments in drug therapy. *Prescriber's Letter* is totally independent, and has no

connection with any pharmaceutical firm. There is absolutely no advertising, or other financial support.

Best Pills Worst Pills

The website of the Health Research Group: <http://www.publiccitizen.org/hrg/>

The website of Best Pills Worst Pills <http://www.worstpills.org>

A newsletter published by the Public Citizen Health Research Group. The most iconoclastic of all of these, reports are often skeptical of the FDA and of the pharmaceutical industry. However, they have proven to be correct over the long haul, and for almost all of the drugs for which they have petitioned FDA removal or black box warnings they have been shown to be correct. A subscription is very inexpensive (online \$15.00/year; print copy can be gotten in special offers for \$10/year) and exposes physicians and physicians in training to a little heard point of view.

The Carlat Psychiatry Report: An unbiased monthly covering all things psychiatric

www.thecarlatreport.com

As it says, it is limited to psychiatry. However many patients treated in medical settings are on psychiatric drugs. It is primarily written by one person, but accepts no money from pharmaceutical companies. Sample issues available on the website.

Oregon Drug Effectiveness Review Project

<http://www.ohsu.edu/drugeffectiveness/index.htm>

<http://www.ohsu.edu/drugeffectiveness/reports/final.cfm>

UK National Institute for Clinical Excellence

<http://www.nice.org.uk/>

Two recent articles relevant to Medicare D and prescribing:

Robert B. Doherty. Assessing the New Medicare Prescription Drug Law. *Annals of Internal Medicine* Vol 141 (5):391-395. September 7 2004.

W. H. Shrank, T. Hoang, S. L. Ettner, P. A. Glassman, K. Nair, D. DeLapp, J. Dirstine, J. Avorn, and S. M. Asch

The Implications of Choice: Prescribing Generic or Preferred Pharmaceuticals Improves Medication Adherence for Chronic Conditions

Archives of Internal Medicine, February 13, 2006; 166(3): 332 - 337.

Helpful sites on the CMS website: (for Medicare D)

www.medicare.gov

In addition to the Medicare Part D, this site has very extensive FAQs on Medicare in general that can be useful for resident teaching. The site is much improved from its inception, and is the only way a physician or patient can figure out the true out of pocket costs likely to result from a particular formulary/plan.

<http://www.cms.hhs.gov/pharmacy/downloads/partsbdcoverageissues.pdf>

A start at explaining what is covered by Part B and Part D. Probably useful to download and print, or keep book-marked because it is not self-evident.

<http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/ModelCoverageDeterminationRequestForm.pdf>

A pdf form for a beneficiary to request a drug exception. However, there is no way a beneficiary will get a drug exception without more information from the doctor. A model for requesting an exception is attached to these handouts and is also available from www.Medicarerights.org.

http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/01_Overview.asp#TopOfPage

Includes the physician information and other useful links such as the standard response sheet from a pharmacist, and the providers letter above

<http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CY07FormularyGuidance.pdf>

2007 Formulary guidance from the Medicare web site. Explains what the plans must or cannot do in formulary creation, and what the rules are for their P & T committees.

Non-government guide to Medicare:

www.medicareinteractive.org

A wonderful web site from the Center for Medicare Rights. Quick answers to coverage questions for providers and patients.

Mysteries of Medicare D explained:

To understand why benzodiazepines, barbiturates, and others are excluded by law under Medicare D: <http://www.medicarerights.org/benzoreport.pdf>

www.kff.org, and any of the advocacy sites have excellent explanations of Medicare D

Resources compiled by Gene Bishop, MD, and Gordy Schiff, MD, March 2007

SAMPLE APPEAL LETTER

Your letterhead here

Re: Patient name:

Address

DOB

Health plan ID #

To Whom It May Concern:

This is a request for an exception for a [non-formulary medication] [tier exception] [continuation of a medication recently removed from the formulary] for the above named patient of mine.

The request is for [drug, dosage, amount, and duration]

[Patient] is under my care for the treatment of [list diagnoses as appropriate].

S/he is unable to take the formulary medications [list medications] because of:

- An adverse reaction (describe)
- A drug-drug interaction
- A contraindication because of (liver) (kidney) disease
- A failure of a therapeutic trial
- A fixed medical belief in the power of the non-formulary medication that has persisted in the face of multiple attempts to dissuade him/her
- Other:

This drug is medically necessary because without it [patient] is at risk for the following adverse consequences:

- Deterioration of the medical condition with risk of hospitalization, permanent disability, or death
- Decline in functional ability that will result in the need for assistance or institutionalization
- Progression of a chronic disease or disability
- Complications of an underlying disease process that have been previously prevented by the medication
- Inability to regain maximum physical and mental functioning
- Other

In addition to the clinical information specific to my patient, this request is supported by the following:

- Treatment guidelines – give reference
- Journal article
- Specialty consultant opinion; consultation enclosed

Please contact me should you require any additional information. I understand that [patient] and I can expect a response within 72 hours of your receipt of this letter. Please fax a copy of the response to me at xxx-xxx-xxxx. I can be reached at xxx-xxx-xxxx.

Signature

IF REQUESTING AN EXCEPTION FOR LOWER COPAY:

[Patient] cannot afford the cost-sharing amount you have designated for this medication. His/her inability to take this medication will seriously jeopardize [patient's]

- Life
- Health
- Ability to regain maximum function

for the reasons stated above. [add documentation available such as rise in LDL, HBA1C, etc] I request that you cover [name of medication] for [name of patient] at a lower cost-sharing tier.

IF REQUESTING AN EXPEDITED EXCEPTION:

In my professional opinion, [patient] must receive an expedited decision in order to obtain [medication] immediately. Failure to receive this medication quickly will seriously jeopardize [patient's] health. I understand that I will receive an answer within 24 hours. My fax number is xxx-xxx-xxxx or I can be reached at xxx-xxx-xxxx.

.....

Additional information on information to include in appeals, and on the appeals process is available from www.medicarerights.org. They also have a sample letter and an appeals manual that can be downloaded from their website after registering.

Medicare Glossary

Actuarially equivalent: The Medicare Modernization Act of 2003 (MMA) term for telling insurance companies that they can vary the benefits offered under the new drug plan as long as the accountants tell them that the overall benefits among the different plans are at least equivalent to the basic plan in the law.

Appeal: A request that you make when you disagree with your insurer's decision not to cover a service you believe you need and should be covered. The ability to appeal Part D denials is mandated by law and the process is regulated by Medicare.

Benefit Period—The way that the Original Medicare Plan measures your use of hospital and skilled nursing facility (SNF) services. A benefit period begins the day you go to a hospital or skilled nursing facility. The benefit period ends when you haven't received any hospital care (or skilled care in a SNF) for 60 days in a row. If you go into the hospital or a skilled nursing facility after one benefit period has ended, a new benefit period begins. You must pay the inpatient hospital deductible for each benefit period. There is no limit to the number of benefit periods you can have

Co-pay: a fixed amount of money that you pay each time you use a service that has a co-pay. For example; \$5 every time you go to a doctor, or \$5 every time you fill a generic prescription

Co-insurance: a percentage of the benefit that you must pay

Creditable Coverage: In regard to the Medicare prescription drug plan, it refers to drug coverage that is at least as good as the basic benefit. If your old coverage is not creditable, you must sign up for new coverage or be subject to a penalty.

Deductible: money that you pay out of pocket before the insurance starts to pay at all

Exceptions: Under the Medicare prescription plan, refers to requests made and granted that allow a non-covered drug in a particular plan to be covered, or a drug to be covered in a lower tier.

Formulary: a list of prescription drugs. In an ideal world, a formulary is a list of the best drugs for each medical condition, and can help a physician know what drugs to choose in a particular situation. Its current common usage is a list of drugs covered by a particular insurance plan.

Tiered formulary: The arrangement of a formulary into different drug categories usually by cost categories, with different co-payments of co-insurance in each tier. Currently used formularies in different plans have from one to five tiers.

Grievance: A complaint you file with your Medicare health plan about its operations, activities or behavior. For example, you may file a grievance if you are dissatisfied with the customer service or how it managed your appeal. **An appeal, not a grievance, is the only way to request a reversal of a denial of coverage.** Each plan can design its own grievance process with minimal regulation by Medicare.

MA: Medicare Advantage Plan when referring to Medicare. In Pennsylvania, many health care providers and others who work with health insurance use MA to refer to Medical Assistance or Medicaid. If you are in a conversation, make sure you are all on the same page.

MA-PD: Medicare Advantage prescription drug plan: a Medicare Advantage plan that includes prescription drugs

Medically Necessary—Services or supplies that are proper and needed for the diagnosis or treatment of your medical condition, are provided for the diagnosis, direct care, and treatment of your medical condition, meet the standards of good medical practice in the local area, and aren't mainly for the convenience of you or your doctor. *This is the Medicare definition. Medically necessary is a legal term, and different insurance companies may use slightly different definitions.*

Medicare-approved amount: The amount of money a physician, hospital, or medical supplier who participates in Medicare can be paid by Medicare for a Medicare covered service. Pharmaceuticals are the only part of Medicare that does not have such cost controls.

Medicaid: A joint Federal-state insurance program for low income persons. Persons can have both Medicaid and Medicare, and when they do, are often called dual eligibles.

Medigap: An insurance plan that pays for costs not covered under traditional Medicare

PDP: Prescription drug plan, free standing, under Medicare Part D.

Point-of-Service: a kind of insurance that some HMOs have that allows you to see non-participating docs for more money

TrOOP: True out of pocket costs; in reference to the Medicare prescription plan refers to the actual amount of money a beneficiary has spent including deductibles and co-pays and co-insurance but excluding the premium. Plan benefits vary depending on how much has been spent on true out of pocket costs.

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Consider adding ethical template for pharmacy benefits from Norm Daniels article from health Affairs