

Health Letter

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Medical Records: Q&A

What is a medical record?

A medical record is a compilation of your medical history; your family medical history; information about your lifestyle; physical examination and laboratory results; medications prescribed; diagnoses and prognoses; results of treatment and procedures undergone; allergies and other risk factors; disabilities and limitations; and participation in research projects. Medical records may also include results of genetic testing used to predict future health. Because of the private, personal nature of this information, access to medical records is restricted.

If you have a primary physician who has provided you with health care over time, orchestrates your care and refers you to other health care practitioners when needed, this person should have your complete medical record, including a summary of hospital events. Otherwise, this information can be quite scattered and difficult to locate, as it is likely to be in different medical offices, clinics, hospitals, laboratories, pharmacies, etc. For this reason, it is wise for you to keep a record of your own medical history, and you should request a copy of your hospital records. Your medical history should include major illness episodes; surgeries and procedures; results of screening and other tests; major prescriptions filled; allergic reactions or adverse effects of medication or treatment; accidents or falls; and pregnancies, miscarriages and births.

Why should I have my medical record?

Having your medical record will make you a more involved and better informed

patient, and will help you be more in control of your own care. It will also facilitate keeping providers informed when you switch physicians or visit a new doctor for the first time. As we become more mobile as a society, having all your medical information together can enhance continuity of care. Your medical record will also provide a good summary of information that you may wish to communicate to others.

Am I entitled to my medical record?

Yes, you are now entitled to your medical record regardless of which state you reside in. The request should be made in writing. In some cases, providers — hospitals or doctors — may require you to fill out a special form requesting the record. They may charge you for copying and handling the record. There may also be an extra charge for providing a copy of an x-ray.

Having an outstanding medical bill should not preclude access to your record.

Who has access to my medical record?

Despite the private nature of much of the information contained in your medical record, this is shared by a number of people, including health care providers and institutions. While you must agree to let others see your record, you may have to share your health information if you want to obtain care and qualify for insurance coverage. Insurance companies usually require you to release your records before issuing you a policy or paying you under an existing policy. Government agencies may also request your medical records to verify claims made through Medicare, Medicaid, Social Security Disability, and Workers Compensation. **Employers can obtain medical information about their employees by asking employees to authorize disclosure of medical records.** If your employer is self-insured, the human resources department is likely to have access to your health-related claims.

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What is HIPAA?

HIPAA refers to the Health Information Portability and Accountability Act (HIPAA), which went into effect in 2003. This law gives consumers the right to see, get a copy of, and amend and supplement their medical records. Consumers' requests must be answered within 30 days, although the deadline may be extended for an additional 30 days under certain circumstances.

HIPAA sets national standards for privacy of health information. But the law applies only to medical records maintained by health care providers, health plans, and health clearinghouses, **and only if the facility maintains and transmits records in electronic form.** Much health-related information exists outside health care facilities and the files of health plans, and is thus not covered by HIPAA.

Can a provider deny me access to my record?

The provider petitioned may deny access to all or part of the record, but must give you a written denial within 30 days. Information that may be denied includes the following:

- Psychotherapy notes that are separate from the medical record;
- Information compiled in reasonable anticipation of or for use in a civil, criminal or administrative action or proceeding;
- Private health information maintained by an entity covered under the Clinical Laboratory Improvements Amendments of 1988, which seek to ensure quality in laboratory testing;
- Under certain circumstances, information requested by an inmate;
- Information obtained in the course of research that includes treatment, if the consumer has agreed to the denial of access while consenting to participate in the research;
- Information contained in records subject to the Privacy Act, which regulates

the collection, maintenance, use and dissemination of personal information by federal executive branch agencies; and

- Information obtained by the provider from someone other than a health care provider under the promise of confidentiality and access to which would be likely to reveal the source of that information.

Can I ask for someone else's record?

In general, only a patient can authorize the release of his or her own medical records. But there are some exceptions, including the following:

Parents of minor children. There are some sensitive services, however, for which minors are entitled to consent on their own and can therefore expect their records to remain confidential. Although federal regulations allow parents access to their children's records, these are usually tempered by provider judgment and long-standing principles of medical ethics

guiding the delivery of confidential care to minors. The American Academy of Pediatrics has long dictated that teens' records be kept confidential when teens seek sensitive services. Some states (e.g., Colorado, New York) have laws specifying that parents may not access the medical records of their minor child who has obtained certain services, such as treatment for sexually-transmitted diseases, drug addiction or abortion. Other states have not addressed the issue, giving health care providers discretion in the matter.

A legal guardian. This is a person who has the authority and duty to care for the personal and property interests of another person, most often called a ward. Usually a ward is not capable of acting on his or her own behalf due to young age, incapacity or disability. A legal guardian of a minor usually has parental rights over the child, in which case the situation described above applies.

An agent. This is someone you have chosen to act on your behalf in a Health Care Power of Attorney. This person acts

as your representative with respect to all health care matters in the event that you are incapacitated. The person you so designate has the same access to your records as you have, including the right to disclose the contents to others.

Do HIPAA regulations override state laws?

HIPAA regulations usually pre-empt state laws, and laws that were contrary to HIPAA were therefore superseded. Nevertheless, states may request an exception to pre-emption from the Department of Health and Human Services. Because HIPAA establishes a floor for the protection of privacy, state laws that are more stringent than the federal rule remain in effect. "More stringent" laws are those that provide individuals greater access to information.

Because there are variations from state to state, patients should check to see the laws that apply within their jurisdiction. State-specific differences include whether or not entities can charge consumers fees for copies of their medical records, and the amount charged. Other differences relate to restrictions on the disclosure of information.

The Center on Medical Record Rights and Privacy at Georgetown University has compiled a state-by-state summary of the prevailing legislation. This is available at <http://hpi.georgetown.edu/privacy/records.html>.

What if I change health care providers, or my provider has moved or gone out of business?

You must make a written request if you want a provider to furnish a copy of your record to another provider. When you decide to change providers, you should ask for a copy of your health records. In the case of physicians who retire or move, or other providers who go out of business, you should get your medical records whenever possible. Providers who retire or move usually place advertisements or notify their patients beforehand. If that is the case, you should request a

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Public Citizen Launches New Blog

Are you looking for a Web site that keeps you informed about the issues Public Citizen cares about, rallies readers to take back their government and tries to deliver it all with a sense of humor? Then check out www.CitizenVox.org.

Public Citizen's communications office launched "Citizen Vox" in February as the organization's latest tool in spreading the word about its mission of protecting health, safety and democracy.

The blog's goal is to highlight Public Citizen's work and tie together the other

blogs maintained by the group's different divisions, as well as direct readers to Public Citizen's online resources, such as WorstPills.org and WhiteHouseForSale.org.

And the blog posts, which are added virtually every day, are increasing in popularity. For example, a Feb. 5 post about an Internet free speech case Public Citizen is defending in West Virginia drew more than 600 visitors that day, with many of the readers clicking through to Public Citizen's Web site at www.citizen.org.

Another popular post about tainted pharmaceuticals pointed readers to an Associated Press story that quoted Sidney Wolfe, M.D., director of Public Citizen's Health Research Group.

"We think it's a great way to get our name out into the blogosphere," said Communications Director Angela Bradbery. "'Citizen Vox' will help us reach a different type of audience – one that might not be as familiar with all the great work we do." ♦

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copy of your medical records. A health care institution that ceases operation must usually provide the local oversight entity (e.g., the local Department of Public Health) with a certified document specifying where its patients' health records will be stored and the procedure for patients, former patients or their authorized representatives to access their records. This may vary from one state to another, so you should check what the "rules of the game" are in the state where you live.

How long are providers required to keep medical records?

Some states require health care providers to keep medical records for six or seven years, but this varies by state. Professional licensure laws regulate how health care is practiced in each state; these may include dispositions on record-keeping and disclosure. You will therefore have to find out what the requirements are in the state where you live or where you received care.

As a practical matter, some practitioners sort their records as "active," "less active" and "inactive." Level of activity refers to the elapsed time since the patient's last visit to the specific provider. The system used will vary from one provider to another.

What happens to my record if my provider dies?

When a provider dies, his or her executor or responsible relative must keep possession of patients' records. In some states, the executor must inform all patients seen within a given time span by notice published in a local newspaper and a letter sent to each patient. The patients' medical records must be kept for a set number of days after the notice. You should use this period to request your medical records. Again, the disposition of records varies by state, so inform yourself of the laws that govern medical records in your state.

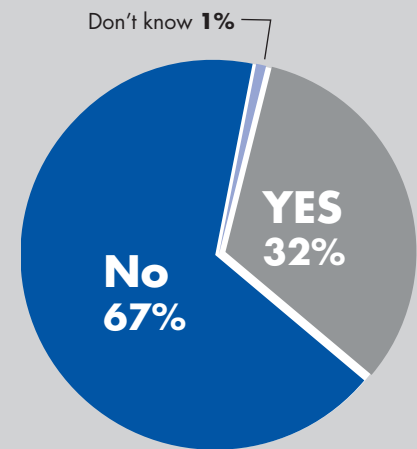
What trends should I be aware of?

Two major trends are affecting the way in which medical information is kept, transmitted and stored. The first is the movement away from paper medical records to electronic records. This has raised many issues on access to information and protection of privacy. A second major trend is the increased diversity of venues through which patients obtain health care. The rise of retail health clinics associated with large chain stores or pharmacies, disease-specific providers, ambulatory surgical centers, and companies facilitating access to care in other countries have complicated

the maintenance of a comprehensive personal medical record. ♦

Most consumers don't have a personal set of medical records

Have you or your family member ever created your own set of medical records to ensure that you and your health care providers have all of your medical information?



Source: Agency for Healthcare Research and Quality, Presentation to the National Advisory Committee on Rural Health and Human Services, March 2005.

Market-Based Failure — A Second Opinion on U.S. Health Care Costs

The following is an article by Robert Kuttner printed in the Feb. 7, 2008, New England Journal of Medicine. We have decided to include this important article for our Health Letter readers. Reprinted with permission.

U.S. health care expenditures rose 6.7% in 2006, the government recently reported. According to the Centers for Medicare and Medicaid Services, total health care expenditures exceeded \$2.1 trillion, or more than \$7,000 for every American man, woman, and child.¹ Medicare costs jumped a record 18.7%, driven by the new privatized drug benefit. Total health care spending, now amounting to 16% of the gross domestic product, is projected to reach 20% in just 7 years.

Relentless medical inflation has been attributed to many factors — the aging population, the proliferation of new technologies, poor diet and lack of exercise, the tendency of supply (physicians, hospitals, tests, pharmaceuticals, medical devices, and novel treatments) to generate its own demand, excessive litigation and defensive medicine, and tax-favored insurance coverage.

Here is a second opinion. Changing demographics and medical technology pose a cost challenge for every nation's system, but ours is the outlier. The extreme failure of the United States to contain medical costs results primarily from our unique, pervasive commercialization. The dominance of for-profit insurance and pharmaceutical companies, a new wave of investor-owned specialty hospitals, and profit-maximizing behavior even by nonprofit players raise costs and distort resource allocation. Profits, billing, marketing, and the gratuitous costs of private bureaucracies siphon off \$400 billion to \$500 billion of the \$2.1 trillion spent, but the more serious and

less appreciated syndrome is the set of perverse incentives produced by commercial dominance of the system.

Markets are said to optimize efficiencies. But despite widespread belief that competition is the key to cost containment, medicine — with its third-party payers and its partly social mission — does not lend itself to market discipline. Why not?

The private insurance system's main techniques for holding down costs are practicing risk selection, limiting the services covered, constraining payments to providers, and shifting costs to patients. But given the system's fragmentation and perverse incentives, much cost-effective care is squeezed out, resources are increasingly allocated in response to profit opportunities rather than medical need, many attainable efficiencies are not achieved, unnecessary medical care is provided for profit, administrative expenses are high, and enormous sums are squandered in efforts to game the system. The result is a blend of over-treatment and under-treatment — and escalating costs. Researchers calculate that between one fifth and one third of medical outlays do nothing to improve health.

Great health improvements can be achieved through basic public health measures and a population-based approach to wellness and medical care. But entrepreneurs do not prosper by providing these services, and those who need them most are the least likely to have insurance. Innumerable studies have shown that consistent application of standard protocols for conditions such as diabetes, asthma, and elevated cholesterol levels, use of clinically proven screenings such as annual mammograms, provision of childhood immunizations, and changes to diet and exercise can improve health and prevent larger

outlays later on. Comprehensive, government-organized, universal health insurance systems are far better equipped to realize these efficiencies because everyone is covered and there are no incentives to pursue the most profitable treatments rather than those dictated by medical need. Although the populations of most countries that belong to the Organization for Economic Cooperation and Development are older than the U.S. population, these countries have been far more successful at containing costs without compromising care (see "Health Care Expenditures in Selected Countries" graph at <http://content.nejm.org/cgi/reprint/358/6/549.pdf>. Data are from the Organization for Economic Cooperation and Development. The growth rate of medical expenditures has been slowest in nations with universal health insurance systems).

Many U.S. insurers do reward physicians for following standard clinical practices, but these incentives do not aggregate to an efficient national system of care. After more than three decades of managed care — and the same three decades of studies by Wennberg and colleagues identifying wide variations in practice patterns — consistent practices are still far from the norm.² Commercial incentives are not fixing what's broken.

Instead, cost-containment efforts have fallen heavily on primary care physicians, who have seen caseloads increase and net earnings stagnate or decline. A popular strategy among cost-containment consultants relies on the psychology of income targeting. The idea is that physicians have a mental picture of expected earnings — an income target. If the insurance plan squeezes their income by reducing payments per visit, doctors compensate by increasing their caseload and spending less time

with each patient.

This false economy is a telling example of the myopia of commercialized managed care. It may save the plan money in the short run, but as any practicing physician can testify, the strategy has multiple self-defeating effects. A doctor's most precious commodity is time — adequate time to review a chart, take a history, truly listen to a patient. You can't do all that in 10 minutes. Harried primary care doctors are more likely to miss cues, make mistakes, and — ironically enough — order more tests to compensate for lack of hands-on assessment. They are also more likely to make more referrals to specialists for procedures they could perform more cost-effectively themselves, given adequate time and compensation. And the gap between generalist and specialist pay is widening.³

A second cost-containment tactic is to hike deductibles and co-payments, whose frank purpose is to dissuade people from going to the doctor. But sometimes seeing the doctor is medically indicated, and waiting until conditions are dire costs the system far more money than it saves. Moreover, at some point during each year, more than 80 million Americans go without coverage, which makes them even less likely to seek preventive care.⁴

The system also has inflationary effects on hospitals' revenue-maximization strategies. Large hospitals, which still have substantial bargaining power with insurers, necessarily cross-subsidize services. The emergency department may lose money, but cardiology makes a bundle. So hospitals fiercely defend their profit centers, investing heavily in facilities for lucrative procedures that will attract physicians and patients. For the system as a whole, it would be far more cost-effective to shift resources from sub-specialists to primary care. But in an uncoordinated, commercialized system, specialists might take their business elsewhere, so they have the leverage to maintain their incomes

and privileges — and thereby distort cost-effective resource allocation.

Defenders of commercialized health care contend that economic incentives work. And indeed they do — but often in perverse ways. The privately regulated medical market is signaling pressured physicians to behave more like entrepreneurs, inspiring some to defect to “boutique medicine,” in which well-to-do patients pay a premium, physicians maintain good incomes, and both get leisurely consultation time. It's a convenient solution, but only for the very affluent and their doctors, and it increases overall medical outlays.

Other doctors opt out by becoming proprietors of specialty hospitals, usually day surgeries. In principle, it is cost-effective to shift many procedures to outpatient settings that are less expensive but still offer high-quality care. In a government-organized universal system, the cost savings can be usefully redirected elsewhere. But in our system, the savings go into the surgeons' pockets, and their day hospitals often have a parasitic relationship with community hospitals, which retain the hardest cases and give up the remunerative procedures needed to subsidize those which lose money.

A comprehensive national system is far better positioned to match resources with needs — and not through the so-called rationing of care. (It is the U.S. system that has the most de facto rationing — high rates of un-insurance, exclusions for preexisting conditions, excessive deductibles and co-payments, and shorter hospital stays and physician visits.) A universal system suffers far less of the feast-or-famine misallocation of resources driven by profit maximization. It also saves huge sums that our system wastes on administration, billing, marketing, profit, executive compensation, and risk selection. When the British National Health Service faced a shortage of primary care doctors, it adjusted pay schedules and added incentives for high-quality care, and the shortage diminished.

Our commercialized system seems incapable of producing that result.

Despite our crisis of escalating costs, dwindling insurance coverage, and deteriorating conditions of medical practice, true national health insurance that would not rely on private insurers remains at the fringes of the national debate. This reality reflects the immense power of the insurance and pharmaceutical industries, the political fragmentation and ambivalence of the medical profession, the intimidation of politicians, and the erroneous media images of dissatisfied patients in universal systems.⁵

Sometimes, we Americans do the right thing only after having exhausted all other alternatives. It remains to be seen how much exhaustion the health care system will suffer before we turn to national health insurance. ♦

No potential conflict of interest relevant to this article was reported.

Kuttner, Robert. “Market-Based Failure — a Second Opinion on U.S. Health Care Costs.” *The New England Journal of Medicine* 358 (2008): 549-551. 26 Feb. 2008 <http://content.nejm.org/>. Copyright © 2008 Massachusetts Medical Society. All rights reserved.

Mr. Kuttner is co-editor of the *American Prospect* and a senior fellow at Demos, a New York-based public policy research and advocacy organization.

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Product Recalls

January 15, 2007 - February 20, 2008

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority. If you have any of the drugs noted here, label them "Do Not Use" and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA Web site is www.fda.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Recalls and Field Corrections: Drugs – CLASS II

Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

Children's Dimetapp Cold & Chest Congestion Syrup, active ingredients (in each 5 mL tsp): Phenylephrine HCl 5 mg and Guaifenesin 100 mg, 4 fl. oz. bottles, OTC; Dosing cups packaged with the product lack the 1/2 teaspoon mark for dosing children 2 to 6 yrs of age. All lots with expiration date 05/2009; Wyeth.

Perphenazine Tablets, USP, 16 mg, 100 tablets, Rx only; 20,402 units; Tablet separation; cracking and splitting of tablets. Lot #: 100 count: T049F07A, exp. date 06/2009; T020G07B, exp. date 07/2009; and T020G07A, exp. date 07/2009; Vintage Pharmaceuticals LLC.

Perphenazine Tablets, USP, 8 mg, 100 and 500 tablets, Rx; 20,402 units; Tablet separation; cracking and splitting of tablets. Lot #: 100 count: T019G07D, exp. date 07/2009 and T019G07C, exp. date 07/2009; 500 count: T019G07B, exp. date 07/2009 and T019G07A, exp. date 07/2009; Vintage Pharmaceuticals LLC.

Robitussin Cough & Cold CF Syrup, active ingredients (in each 5 mL tsp): Dextromethorphan HBr 10 mg, Guaifenesin 100 mg, Phenylephrine HCl 5 mg; 4 fl. oz., 8 fl. oz. and 12 fl. oz. bottles, OTC; Dosing cups packaged with the product lack the 1/2 teaspoon mark for dosing children 2 to 6 yrs of age. All lots with expiration dates 01/2008 to 08/2009; Wyeth.

Robitussin Cough & Congestion Syrup, active ingredients (in each 5 mL tsp): Dextromethorphan HBr 10 mg and Guaifenesin 200 mg; 4 fl. oz. and 8 fl. oz. bottles, OTC; Dosing cups packaged with the product lack the 1/2 teaspoon mark for dosing children 2 to 6 yrs of age. All lots with expiration dates 05/2008 to 08/2010; Wyeth.

Robitussin Cough DM Syrup, active ingredients (in each 5 mL tsp): Dextromethorphan HBr 10 mg and Guaifenesin 100 mg; 4

fl. oz., 8 fl. oz. and 12 fl. oz. bottles, OTC; Dosing cups packaged with the product lack the 1/2 teaspoon mark for dosing children 2 to 6 yrs of age. All lots with expiration dates 10/2007 to 08/2010; Wyeth.

Robitussin Head & Chest Congestion PE Syrup, active ingredients (in each 5 mL tsp): Phenylephrine HCl 5mg and Guaifenesin 100 mg; 4 fl. oz. bottles, OTC; Dosing cups packaged with the product lack the 1/2 teaspoon mark for dosing children 2 to 6 yrs of age. All lots with expiration dates 01/2008 to 04/2009; Wyeth.

Robitussin PE Syrup, active ingredients (in each 5 mL tsp): Pseudoephedrine HCl 30 mg and Guaifenesin 100 mg; 4 fl. oz. and 8 fl. oz. bottles, OTC; Dosing cups packaged with the product lack the 1/2 teaspoon mark for dosing children 2 to 6 yrs of age. All lots within expiration; Wyeth.

Robitussin Sugar Free Cough Syrup, active ingredients (in each 5 mL tsp): Dextromethorphan HBr 10 mg and Guaifenesin 100 mg; 4 fl. oz. bottles, OTC; Dosing cups packaged with the product lack the 1/2 teaspoon mark for dosing children 2 to 6 yrs of age. All lots with expiration dates 10/2007 to 02/2010; Wyeth.

Robitussin-CF Syrup, active ingredients (in each 5 mL tsp): Dextromethorphan HBr 10 mg; Guaifenesin 100 mg, Pseudoephedrine HCl 30 mg; 4 fl. oz., 8 fl. oz., and 12 fl. oz. bottles, OTC; Dosing cups packaged with the product lack the 1/2 teaspoon mark for dosing children 2 to 6 yrs of age. All lots within expiration; Wyeth.

Simvastatin Tablets USP, 20 mg, 1,000-tablet bottle, Rx only; 1,447 bottles/1,000-tablet bottles; Product may contain some Carvedilol 25 mg tablets. Lot # 02S179, exp. date 08/2009; Teva Pharmaceuticals USA.

CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at (800) 638-2772. The CPSC web site is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Drug or Supplement, Problem, Recall Information

Air Compressors. Protective covers on the Campbell Hausfeld and Husky Air Compressors' motors are not made from proper flame retardant material and can ignite, posing a fire hazard. Campbell Hausfeld, (800) 241-0448 or www.chpower.com.

ATVs. The Polaris All-Terrain Vehicles (ATVs) can have defective Electronic Control Modules (ECM) that overheat, posing a fire and burn hazard to riders. Polaris Industries Inc., (888) 704-5290 or www.polarisindustries.com.

Baby Sterling Silver Teethers. The hearts and cars on the Heart and Car Sterling Silver Teethers can break off, posing a choking hazard to infants. Elegant Baby and Baby Needs Inc., (800) 334-5321 or www.elegantbaby.com.

Boys' Hooded Sweatshirts. The Karl Kani Boys' Fleece Hoody Sweatshirts have a drawstring through the hood which poses a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist by drawstrings in upper garments, such as jackets and sweatshirts. Siegfried & Parzifal Inc., (866) 268-2868.

Car Charging Units. The batteries in the Car Charging Units (included with LL Bean Airbeds) can overheat when the car engine is running, causing the battery charging unit to burst. This can pose an injury hazard to consumers. L.L. Bean, (800) 555-9717 or www.llbean.com.

Children's Hooded Sweatshirts. The Bonafide Love Hooded Children's Sweatshirts have a drawstring through the hood, which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist by drawstrings in upper garments, such as jackets and sweatshirts. Seventy Two Inc., (626) 330-8027 ext. 170.

Children's Sketchbooks. The paint on the Sketchbooks with Colored Spirals' metal bindings contains excessive levels of lead violating the federal lead paint standard. eeBoo Corp., (800) 791-5619 or www.eeBoo.com.

Children's Table and Chair Sets. The surface paint on the Children's Table and Chair Sets contains excessive levels of lead, violating the federal lead paint standard. Netshops, (866) 558-9485 or www.netshops.com.

Cinderella Battery-Powered Toy Cars. The wires under the hood of the Cinderella 12-Volt Electric Ride-On Vehicles and/or in the battery compartment under the seat can short circuit, posing a fire and burn hazard to children riding in the car. Dumar International USA, (866) 424-0500 or www.dumarusa.com.

Cranium Cadoo Board Games. The surface paint on the die contains excessive levels of lead, violating the federal lead paint standard. Cranium Inc., (877) 272-6486 or www.cranium.com.

Crib Toys. The anchors that hold the straps to the back of the Baby Einstein Baby Neptune™ Soothing Seascape Crib Toys can detach, posing a choking hazard to young children. Kids II Inc., (866) 203-6788 or www.kidsii.com.

Cribs. Spindles on the drop-side of the Wendy Bellissimo Hidden Hills Collection Drop-Side Cribs could loosen creating a gap that poses an entrapment and strangulation hazard. Bassettbaby, (800) 308-7485 or www.bassettbaby.com.

Egg Shaker Toy Instruments. The end cap can detach from the Transparent Toy Egg Shakers and allow the small beads to spill out, posing choking/aspiration hazards to young children. West Music Company, (800) 397-9378 or rcousins@westmusic.com.

GE Gas Clothes Dryers. A short circuit in the GE Gas Clothes Dryer's wiring poses a shock hazard to consumers with ungrounded dryers. GE Consumer & Industrial, (866) 324-3732 or <http://geappliances.com>.

Girls' Bicycles. The Trek MT220 Girls Bicycle's frame can break during use, causing the rider to lose control and suffer injuries. Trek Bicycle Corp., (800) 373-4594 or www.trekbikes.com.

Girls' Bracelet Sets. Surface paint on the pearl white beads of the bracelet in the A Life of Faith Charm Bracelet Sets contains excessive levels of lead, violating the federal lead paint standard. Mission City Press, (800) 840-2641 or www.alifeoffaith.com/bracelet_recall.html.

Girls' Hooded Jackets. The Girls' Hooded Jackets have a drawstring through the hood which poses a strangulation hazard to children. In February 1996, CPSC issued guidelines to help

CONSUMER PRODUCTS

prevent children from strangling or getting entangled on the neck and waist by drawstrings in upper garments, such as jackets and sweatshirts. AJBlue LLC, dba Apollo Jeans, (212) 398-6585.

Hot Glue Guns. Crafters Square Hot Melt Mini Glue Guns can short circuit, causing the gun to smoke and catch fire. This poses fire, burn and shock hazards to consumers. Dollar Tree Stores Inc., (800) 876-8077 or www.dollartree.com.

Inversion Therapy Tables. A weld in the center of the Inversion Therapy Tables can fail when the table is in an inverted position, posing a fall hazard to consumers. Stamina Products Inc., (888) 782-6462 or www.staminaproducts.com.

Jar Candles. The Jar candles can burn with a high flame, posing a fire hazard. The Wick & Petal Co., (317) 441-8008 or www.wickandpetal.com.

John Deere Tractors. The forward drive pedal of John Deere Compact Utility Tractors can get stuck, posing a risk of loss of control and injury to the operator and bystanders. Deere & Company, (800) 537-8233 or www.johndeere.com.

Magnetic Construction Sets. Small magnets inside the building pieces of Battat Magnabild Magnetic Building Systems can fall out. Magnets found by young children can be swallowed or aspirated. If more than one magnet is swallowed, the magnets can attract each other and cause intestinal perforations or blockages, which can be fatal. Battat Inc., (800) 247-6144 or www.battatco.com.

Pendants and Candle Charms. The Pendants and Candle Charms contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Benjamin International, (888) 249-7639 or www.benjamininternational.com.

Photo Frames. Surface paint on the Hanging Photo Frames contains excessive levels of lead, violating the federal lead paint standard. The Gift Wrap Co., (800) 443-4429 or www.giftwrapcompany.com.

Play Mats. The paint on the Tic Tac Turtle Toss Mats contains excess levels of lead, violating the federal lead paint standard. Discount School Supply, (800) 993-3603 or www.discountsschoolsupply.com.

Remote-Controlled Toy Helicopters. The rechargeable battery contained inside the Remote-Controlled Helicopter Toys can catch

fire during charging, igniting the helicopter and nearby combustible materials. This poses a burn or fire hazard to consumers. Soft Air USA Inc., (817) 210-4181 or Bhook@softairusa.com.

Round and Egg-Shaped Candles. The Round and Egg-Shaped Decorative Candles' exterior coating can ignite, posing a fire hazard. Pottery Barn, (888) 922-9245 or www.potterybarn.com.

Spiderman Water Bottles. Screws under the Spiderman® Water Bottle's lid can come loose and fall into the cup, posing a choking hazard to children. Fast Forward LLC, (877) 244-4433.

Taper and Votive Candles. The Nordstrom "At Home" Taper and Votive Candles' exterior coating can ignite, posing a fire hazard. Nordstrom Inc., (800) 804-0806 or www.nordstrom.com.

Tea Light Candles. The "Embers" Tea Light Candles have a clear, plastic shell that can melt or ignite, posing a fire and burn hazard to consumers. Christmas Tree Shops Inc., (888) 287-3232 or www.christmastreeshops.com.

Toy Gardening Tools. The paint on the Toy Gardening Hand Rakes contains excessive levels of lead, violating the federal standard on lead in paint on toys. Downeast Concepts Inc., (800) 343-2424 or www.backyard-beyond.com.

Toy Racing Cars. Surface paint on the Toy Racing Cars contains excessive levels of lead, violating the federal lead paint standard. OKK Trading Inc., (877) 655-8697 or www.okktrading.com.

Toy Stoves. A metal bracket connecting the door to the "My First Kenmore" Play Stoves can cause a tip-over when the door is opened. This poses a risk of injury to young children. Sears, Roebuck and Co. and Kmart Corp., (800) 659-7026 or either www.sears.com or www.kmart.com.

Toy Wooden Block and Train Sets. Surface paint on some pieces of the Big Wooden Blocks and Jumbo Wooden Train Sets contains excessive levels of lead, violating the federal lead paint standard. Christmas Tree Shops, (888) 287-3232 or www.christmastreeshops.com.

Toy Wrestler Dolls. The surface paint of the Toy Wrestler Figures contains high levels of lead, violating the federal lead paint standard. A.A. of America Inc., (888) 822-8697 or www.aatoys.com.

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system. This in turn means better access to organs, shorter waiting times and more favorable survival rates for those who are savvy on how the system operates.

In the U.S., the responsibility for bringing organ donors and recipients together, for kidneys and other organs, falls to a non-profit organization, the United Network for Organ Sharing (UNOS). This in turn links all professionals involved in the nation's organ donation and transplantation system in the Organ Procurement and Transplantation Network (OPTN), which includes all transplant programs and organ procurement organizations (OPO). A central computer ranks potential candidates in terms of clinical information and time spent on the waiting list. In the case of kidneys, when an organ becomes available the local procurement organization (of which there are 58 nationwide) tells UNOS, which generates a list of potential recipients. If a perfectly matched recipient is identified, the kidney is offered to that individual regardless of location in the U.S. In the absence of a perfect match, the kidney is first offered to the most compatible potential recipient listed locally. The local transplant team has an hour to decide whether or not it accepts the organ, the urgency of the decision reflecting the limited viability of the organ. If the organ is not accepted, the OPO continues to offer it regionally then nationally until it is placed.

As described so far, there is nothing in the system to favor any particular group. How, then, is the allocation process skewed? There are two sources of bias: one is the marked geographic disparity in the availability of organs, and the other is the possibility of registering for a transplant in more than one OPO. Each of these has different effects, and will be dealt with consecutively.

Some local OPOs have a much higher proportion of donors-to-transplant candidates than others, creating marked geographic disparities that in turn affect the odds of transplantation and the length of the waiting time. Indeed, there is a

tenfold difference in median waiting times to procure an organ between the OPOs with the highest and lowest donor-to-transplant ratios. Thus, as acknowledged in a discussion paper prepared for the President's Council on Bioethics, "... geography remains a pivotal criterion in organ allocation and where a transplant candidate is registered remains a potent factor in determining whether he or she

Organ distribution is in fact skewed in favor of those who are better able to navigate the system.

ultimately receives an organ." Most persons awaiting a kidney register in the nearest OPO. This is not only most convenient, but also shortens the distance between the donor, the recipient and the transplant hospital, which can enhance the functioning of the organ when transplanted. But because some areas have multiple OPOs within driving distance while others rely on OPOs with large, multi-state catchment areas, place of residence can severely curtail the options available to different groups of patients. The issue of geographic disparities is somewhat mitigated by allowing "multiple listing:" registering at two or more transplant centers in different local areas. Those who have access to several OPOs can therefore avail themselves of this possibility. This means that given candidates are in effect waiting in different queues, thereby increasing their chances of obtaining a kidney, or getting one sooner. A study of candidates added to the OPTN list between July 1, 1995, and June 30, 2000, found that multiple-listed candidates had a relative rate of transplant that was 1.88 times that for single-listed candidates, with a waiting time that was almost 50 percent less.

But by allowing this option, the system favors some candidates at the expense of others. Given that many more persons are awaiting kidneys than there are available organs, the allocation process is the ultimate zero-sum game: moving up in the queue means that others are pushed farther behind. And those that are multiple-listed are a distinct set of the candidate pool as a whole. The same study that examined data from 2000 to 2005 found that those with a high PRA (panel reactive antibody,

indicating a greater likelihood of organ rejection), 18 to 34 years of age, with a college education or higher and with private insurance were each significantly more likely to be on multiple lists. Conversely, those who were very young (ages 0 to 17), female, African-American, have type A or AB blood types and were covered by Medicaid or an HMO, were each significantly less likely to multiple-list. In addition, the researchers who did the study of organ allocation have suggested that those who are on several registries are less acutely ill than their single-listed counterparts.

While the possibility of registering in multiple lists is theoretically open to all, only a small fraction of kidney transplant recipients avail themselves of the option. Between 1987 and 1990 the proportion was estimated at 6.8 percent, decreasing to 5.8 percent between 1995 and 2000. For the latter period, an estimated 7.3 percent of kidney transplant recipients were listed at centers in more than one OPO at the time of their transplant. And, based on 1995-2001 data, UNOS calculates that 6.6 percent of those on the kidney waiting list were multiple listed.

There are several reasons for the relatively small number of transplant candidates registered at different sites. Some are unaware of the possibility. Others who know about it may be unable to travel to different centers, or to abide by the conditions that registration entails. These conditions may vary from one OPO to another, so applicants must be willing to comply with different requirements. (For example, the patient must be able to reach the transplant center within a certain amount of time if he or she receives an organ offer.) Here, geography again plays a role. Patients who live within a reasonable driving distance from several OPOs (as is the case in Texas; New Jersey; New York City; Ann Arbor, Michigan; and Toledo, Ohio) may therefore have an advantage in registering at multiple centers.

In addition to privileging a given group of patients, multiple listing adds costs to the system. And because most patients awaiting kidneys are covered by Medicare, the cost of single and multiple listing is borne by taxpayers and the public at large. Charges include evaluation

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testing and registration fees at each of the additional transplant centers where the patient registers. The registration fee is \$502. Additionally, transplant candidates must undergo monthly antibody screenings for every center where they are listed; these cost approximately \$250 per month per center. A medical evaluation is required for each listing, and this costs an average of \$12,300 per patient. Patients who are multiple-listed therefore account for costs that double or more what their single-listed counterparts generate. And because Medicare generally covers 80 percent of the costs of multiple evaluations, patients may have to bear significant out-of-pocket expenses, thus deterring those who cannot afford to do so and further increasing the prevailing socio-economic disparities in access to kidneys.

Concerns over equity and cost have prompted UNOS to revisit the policy permitting multiple listing at different times over the past 20 years. In 1988, equity concerns led to a recommendation to rescind the policy and prohibit multiple listing. But public comments reflected opposition to the change, and the policy remained in effect. The issue was reopened in 1994, and debated again between 2002 and 2004. Yet national policy has remained unchanged, even in the face of growing evidence that multiple

listing creates unequal opportunities to receive a needed transplant.

During this extended period, only New York State has taken action. Citing the unfairness of the national system, in 1990 the state passed legislation prohibiting

National policy has remained unchanged, even in the face of growing evidence that multiple listing creates unequal opportunities to receive a needed transplant.

OPOs in the state from accepting individuals on their waiting lists if they were already registered at any other in-state OPO. The ban had no effect on those who were already multiple-listed, effectively grandfathering those who had registered prior to the law's enactment. Nor did it prohibit multiple listing at out-of-state transplant centers. An assessment of the law's effects published

in 1998 found that the ban resulted in a 66 percent reduction in the rate of multiple listing for New York patients; at the same time, multiple listing declined by 87 percent at in-state OPOs.

A simulation looking at the effects of New York's ban on access to transplantation found that, because the odds of multiple listing were relatively small, even a completely effective ban on such listing tended to have little impact on median waiting times. Among those demographic groups who tended to be at a disadvantage prior to the ban (Latinos, African Americans) the waiting list was shortened by only two and three weeks, respectively. Conversely, those who had previously benefited from multiple listing (who lived in areas with higher incomes and higher levels of education) had their

median waiting times lengthened by one and two weeks, respectively. The effects of the ban on equity were therefore limited. Moreover, because some patients circumvented the ban by multiple registering at out-of-state centers, the ban had "the unintended effect of making the multiple listing options available to a smaller, more affluent, subset of patients."

The results of the state-specific ban suggest that, as long as patients have mobility, some will benefit at the expense of others, and that to be more equitable, the ban would have to be national in scope. The authors of the New York study recommend that waiting lists be consolidated by having each OPO cover a larger area as way to reduce the benefits of multiple listing and perhaps improve the matching of donor organs to transplant recipients. This would also reduce the significant geographic disparities among OPOs.

Even if the effects of the ban were marginal in the one state in which it was adopted, the practice of multiple listing is still intrinsically unfair as a matter of policy. And for taxpayers to be paying for a practice that benefits the advantaged at the expense of the disadvantaged is particularly egregious.

Our recommendation is that UNOS change its policy and prohibit the practice of multiple listing. They have already recognized that this practice causes inequities and, by "stacking the deck" in favor of certain categories of patients, has the potential to enhance mistrust of the system. Twenty years is much too long to defer this much-needed decision. Delaying justice has no excuse when what is at stake is a matter of life and death. ♦

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Scarce Kidneys: Why U.S. Transplantation Policies are Inherently Inequitable and How They Can Be Changed

The issue of who gets what organ is an important one in the U.S.; it is particularly relevant with respect to kidneys, where the gap between supply and demand is distressingly wide and expected to get wider over time. At present, more than 70,000 individuals in this country are waiting for a donated kidney. The shortage of kidneys means that more than 10 persons die waiting every day, giving greater importance to the ethics and fairness of waiting lists and how these operate.


Although John F. Kennedy said “Life is unfair,” this does not mean that fairness is not a worthy goal. Nor does it mean that we have to tolerate unfairness when it can be redressed. Organ transplantation is certainly one area in which health care

disparities are particularly insidious. As a result, the World Medical Association has adopted a policy on human organ donation and transplantation that seeks to insure equity and utility in the distribution of scarce organs. “Equity” means that the allocation of organs be fair and just, and that the system of organ distribution not be stacked in favor of a particular group. “Utility” requires that waste be avoided and that organs be distributed so that benefits are maximized. At times, these two values may be in conflict, and what is fair may not be efficient, thereby running counter to “utility.” Given this possibility, many governments have explicit policies governing different aspects of organ donation and allocation. Reasonable and fair criteria to be considered in allocating

organs thus include urgency and severity of medical need; length of time on waiting list; and probability of success measured in terms of expected additional lifespan, minimization of complications, and size, tissue and blood compatibility between donor and recipient.

In the U.S., while anonymous donors often assume that their organs will be given to the sickest patients, organ distribution is in fact skewed in favor of those who are better able to navigate the system. Because this ability is correlated with residence, education and resources, some population groups, by virtue of their geographic location or, often, their socio-economic status, fare noticeably better than others under the current

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
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