

Managed Care COMPLIANCE ALERT

News & Analysis On Regulatory Compliance & Quality Assurance For Managed Care

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We welcome your comments and suggestions!

*Quality***CMS TO OFFER 'LOCAL INITIATIVE' AS QAPI OPTION**

Ever anxious to keep existing managed care organizations in the Medicare+Choice program, the **Centers for Medicare & Medicaid Services** continues to scale back quality requirements in the name of decreasing red tape.

The Bush administration's latest white flag appeared in changes to the Medicare Managed Care Manual's section on Quality Assessment and Performance Improvement projects. Beginning in 2003, according to the manual, M+COs will only have to initiate one QAPI project per year.

Under the Quality Improvement System for Managed Care requirements, M+COs until this year had to run two QAPI projects — one national project selected by CMS and one internal project selected by the individual M+COs. In 2002, the QAPI project required M+COs to report on breast cancer screening rates using HEDIS data.

The **Department of Health and Human Services** is following through on a promise Secretary **Tommy Thompson** made last summer in Operational Policy Letter No. 133 to reduce administrative burdens on M+COs, which had complained about QAPI's duplicative and expensive requirements.

In 2003, CMS is eliminating the M+CO-selected project and will only require M+COs to perform the national QAPI project. The 2003 QAPI project requires M+COs to implement either a culturally and linguistically appropriate services program or a clinical health care disparities program.

In 2004, M+COs will be able to choose whether they want to perform the CMS-chosen national project, which will center on diabetes, or "a local marketplace initiative," according to the manual. In a local marketplace initiative, an M+CO would partner with a Medicaid or other state agency, a Quality Improvement Organization (formerly known as a Peer Review Organization), or a private purchaser.

If they choose a QAPI local initiative in 2004, under QISMC, M+COs must take into account "the prevalence of a condition among, or need for a specific service by, the organization's enrollees; enrollee demographic characteristics and health risks; and the interest of consumers in the aspect of care or services to be addressed," says CMS. ❖

Editor's Note: To see the new sections of the

Medicare Managed Care Manual, go to www.cms.hhs.gov/manuals/116_mmc/mc86c05.asp#s30.

*Prescription Drugs***PHARMACISTS STILL WARY OF CMS Rx CARDS**

Refusing to give up, the Bush administration is making another play for its struggling prescription drug card proposal. The **Centers for Medicare & Medicaid Services** Aug. 30 announced it would release a final rule implementing Medicare-endorsed drug cards, despite the continued threat of a legal challenge by the pharmacy industry.

President **George Bush** last July introduced the idea of CMS endorsing cards offered by private drug companies, but pharmacy groups — including the **National Association of Chain Drug Stores** and the **National Community Pharmacists Association** — challenged CMS' authority to unilaterally launch such a program without going through the customary administrative channels.

The NACDS and NCPA sued CMS in federal court, alleging the agency lacked the proper statutory authority to implement the program. A District of Columbia federal court agreed last September, and the plan was put on hold while CMS scrambled to redesign it. In March 2002, the agency came up with a proposed reg, which it submitted for public review.

The final rule establishing the Medicare-Endorsed Prescription Drug Card Assistance Initiative appeared in the Sept. 4 *Federal Register*. Under the rule, CMS-endorsed card sponsors will offer cards with discounts of up to 25 percent or more. "These savings must be shared with enrollees, either directly or indirectly through pharmacies as lower prices or pharmacy services," says CMS.

The new card differs from the initial proposal in several ways, according to CMS. More information on drug prices will be available to beneficiaries; card sponsors are now explicitly required to secure rebates or discounts; sponsors can offer two program designs that differ in price; and programs must ensure stable formularies and prices.

In a nod to the pharmacists' concerns, the final rule requires card plans to "provide improved access to retail pharmacies, in both urban and rural areas." It also changed the qualifying criteria for pharmacies to offer the cards.

But the agency knows it's not out of the woods yet. "We expect the pharmacists to take us back to court, saying we still don't have the authority," a CMS official tells **Eli**.

NACDS General Counsel **Larry Kocot** Aug. 30 issued a statement warning that while the association appreciated the administration's effort to solicit public comment, his organization has "seen no evidence to suggest that the administration can satisfy the most important aspect of the preliminary injunction order that stopped the original program — that is, that CMS does not have the authority to conduct this program."

Not that the pharmacists lack the ability to sculpt a discount card program. The NACDS is planning to launch its own card in partnership with pharmaceutical companies. "That shows it's a good idea," the CMS official comments. **Pfizer**, for example, offers a card to low-income seniors. CMS' card is "open to everybody," says the official.

CMS is casting the drug card rule as an exercise of its authority to educate beneficiaries, the CMS official points out. The rule is an "initiative [to] promote the use of generic drugs by educating beneficiaries about generic drugs and providing information on generic alternatives," says the agency. CMS' authority under its education powers has been construed very broadly for the last 35 years, explains the official, adding that the rule will help "educate beneficiaries about how to save money through the use of tools that are available."

Congress has had the opportunity through several bills to grant CMS explicit regulatory authority to run such a program, but it has not yet delivered, Kocot charged. The CMS official acknowledges that the agency hasn't seen any bills authorizing CMS to introduce its drug card plan. But some of the Medicare prescription drug benefit bills introduced in Congress before the summer recess included provisions about drug cards, the official says, and CMS Administrator **Tom Scully** is confident that if a drug benefit is passed, it would include the necessary authority for CMS to run the discount card program.

Even if Congress passes a drug benefit, the official says, "it would be a number of years before the benefit goes into place." The card program, on the other hand, "will happen much sooner — in the spring, according to Scully." And the discounts available through the CMS card program might be available to help any drug benefit grow.

"This gives us a starting point to create a

benefit," the CMS official says of the card plan. "Right now, we don't have the infrastructure in place" for a full drug benefit, but the cards "would be a step in that direction." ❖

Health Care Transactions

DON'T OVERLOOK TRANSACTIONS COMPLIANCE EXTENSION

There's barely a month left before HIPAA electronic transactions standards go into effect, and Medicare+Choice organizations could be caught out on a HIPAA compliance limb unless they file for a one-year extension soon.

Filing the model plan for Health Insurance Portability and Accountability Act compliance, which the **Centers for Medicare & Medicaid Services** requires for the one-year extension, should be in capital red letters on the top of this month's to-do list, experts warn.

Legislation passed late last year allows covered entities to secure a one-year extension on compliance — from Oct. 16, 2002 to Oct. 16, 2003 — if they submit a brief HIPAA compliance plan to CMS by Oct. 15, 2002, CMS COO **Ruben King-Shaw Jr.** points out in an Aug. 26 statement.

The model plan form CMS has furnished for plans and providers to fill out is online at www.cms.hhs.gov/hipaa/hipaa2/ascaform.asp. Alternatively, covered entities can submit the plan by mail, but CMS prefers online submissions.

The online form takes only about a half hour to complete, says **Mark Fuentes**, consultant with **The Anesis Group** in Knoxville, TN. "[D]on't wait until Oct. 14 to do it," he warns. Oct. 1 should be the latest deadline plans set for themselves in submitting the form, Fuentes judges. The online form offers M+COs a much easier way to comply, and it generates a confirmation page that can be used to prove they submitted their extension plans.

No such confirmation comes with a mailed submission, notes attorney **Robert Markette Jr.** with **Gilliland & Caudill** in Indianapolis. The address for the HIPAA extensions is a post office box, so it would be difficult to impossible to receive certification that the document was received, Markette notes. "Most providers will be more comfortable having something from HHS to show as proof of filing their compliance plan."

If you're not quite sure if your organization will be HIPAA-compliant by Oct. 15, or if you're not sure you're a covered entity under

HIPAA, go ahead and file for the extension, Markette urges. There's a place on the form to indicate that you're still trying to determine if you're a covered entity, Markette explains: "Filing for the extension will not transform a non-covered entity into a covered entity, so there is nothing to lose by filing."

Just because the feds have granted a one-year extension on HIPAA transactions compliance doesn't mean your HIPAA worries are postponed a year, Fuentes warns. Plans and providers should be carefully scouring their policies and procedures for HIPAA-related issues as part of their overall plan to come into HIPAA compliance.

For example, many organizations have clauses in their policies that say employees can't receive personal e-mails or cell phone calls. "You need to enforce that provision or take it out" under HIPAA, Fuentes warns. Since it's nearly impossible to monitor all e-mails and calls employees receive, it's more practical to say employees should receive few or nominal personal messages, he advises. ❖

Compliance

OIG GREEN-LIGHTS INTERNET DM PROGRAM

The **HHS Office of Inspector General** in August issued two advisories that show the feds are still very interested in what Medicare+Choice and disease management organizations are giving Medicare beneficiaries for free.

The OIG Aug. 29 issued an advisory bulletin outlining for plans and providers the permissible limits on gifts for Medicare beneficiaries. In competitive markets, M+COs sometimes offer potential members free gifts for signing up. The bulletin makes it clear that gifts worth more than \$10 in any one instance or \$50 over the course of a year violate the Social Security Act's prohibition on remuneration paid to influence beneficiary choice.

The OIG warned providers against shady business consultants last June and, in the latest advisory, seeks to offer more "bright-line guidance that

will protect the Medicare and Medicaid programs, encourage compliance, and level the playing field among providers."

Exceptions to the \$10/\$50 rule allow plans and providers to give beneficiaries more expensive items or services if they fall into one of five statutory exceptions: waivers of copays based on financial need, copay differentials in health plans, incentives designed to promote the delivery of certain preventive services, waivers of hospital outpatient copays that exceed minimum copayment amounts in the Medicare hospital outpatient fee schedule and practices protected by one of the safe harbors to the anti-kickback statute.

In addition, providers can safeguard themselves by securing an advisory opinion from the OIG. The bulletin also reveals that the OIG is contemplating two new exceptions to the general rule: one for complimentary local transportation and another for free goods offered to beneficiaries who participate in certain clinical studies.

The OIG wraps up its discussion with a warning to providers whose practices may not be kosher: Wind down your programs, and do it fast. To see the bulletin, go to <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

In another advisory opinion issued Aug. 30, the OIG addresses whether a disease management program run for members of MCOs via the Internet and funded through ads from pharmaceutical companies violates federal anti-kickback or inducement statutes. Not in that instance, decides the OIG, but if the intent to induce or reward referrals were there, such an arrangement could run afoul of the anti-kickback statute.

The requestor of the opinion seeks to set up a program in which it would contract with MCOs and employer-based health plans to provide a drug and behavior compliance program for members over the Internet, according to the OIG. Members and primary care physicians would get incentives to use the program, and

Managed Care Litigation Update

PACIFICARE GIVEN SECOND CHANCE TO COMPLY WITH AIDS LAW

A Los Angeles-based foundation for AIDS and HIV care has dropped a lawsuit it filed against **PacificCare of California** — but it has warned that it

might refile the suit.

The lawsuit by **The AIDS Healthcare Foundation** alleged that PacificCare did not properly manage the care — particularly, the access to specialists — of its beneficiaries with AIDS. The foundation has called off the dogs, it says,

so that PacifiCare can have a chance to redeem itself by complying with new regulations recently passed by the state's **Department of Managed Health Care** and signed by Gov. **Gray Davis** (D).

The law mandates that qualifying HIV-positive members in California HMOs receive standing referrals to specialists.

The foundation will file the lawsuit again if it decides that PacifiCare is not complying with the new regulations, announced **Michael Weinstein**, the foundation's president. ❖

APPELLATE PANEL CHIPS AWAY AT ERISA PREEMPTION

A Sept. 17 ruling from the 5th U.S. Circuit Court of Appeals shows the appellate panel moving toward a narrower view of ERISA preemption — and potentially putting Texas health plans at risk of costly lawsuits from aggrieved enrollees.

The ruling consolidates complaints from four separate plaintiffs, **Ruby Calad**, **Walter Thorn**, **Juan Davila** and **Gwen Roark** against health maintenance organizations **Humana Inc.**, **CIGNA Healthcare of Texas**, and **Aetna U.S. Healthcare**. Each sued their respective HMOs under state law, alleging that the HMOs negligently refused to cover treatments recommended by their doctors in violation of the Texas Health Care Liability Act. The health plans all claimed that the lawsuits were preempted by the Employee Retirement Income Security Act.

In three of four cases the 5th Circuit sided with the plaintiffs, holding that ERISA did not preempt their claims — and the court only reluctantly conceded that the fourth plaintiff's malpractice claim was preempted.

In the Calad and Davila cases, the court concluded, citing the U.S. Supreme Court's 2000 decision *Pegram v. Herdrich*, that since the HMOs were not acting as plan fiduciaries when they denied medical treatment, § 502(a)(2) of ERISA "cannot cover (or completely preempt) their THCLA claims." The court added that the HMOs couldn't rely on § 502(a)(1)(B) either, since that provision "creates a cause of action for breach of contract: When a plan administrator incorrectly interprets the plan to deny benefits, the patient may sue to recover the benefits."

"By contrast," the appellate panel held, "Calad and Davila assert tort claims; they have not sued their ERISA plan administrator, nor do they

challenge his interpretation of the plan."

As for Thorn, the court ruled that he stated only state law causes of action, that the district court never had jurisdiction in the first place, and that the case belonged in state court.

Roarke's case — which centered on § 514 preemption — presented a different story, and the 5th Circuit reluctantly concluded that it was bound by its earlier ruling in *Corcoran v. United Healthcare Inc.* "If we were writing on a clean slate, or deciding this en banc, the Roarks would have a strong case against ERISA preemption," the court held. "But, as a panel, we are bound by *Corcoran*." ❖

SENTENCING AGREEMENT DOESN'T TRUMP OIG EXCLUSION CLOUT

The fact that a psychiatrist who defrauded Medicare agreed with the **Department of Justice** that a five-year prison term would be an appropriate sentence for his crime couldn't stop the **HHS Office of Inspector General** from excluding him from Medicare for a far longer period.

So ruled the 10th U.S. Circuit Court of Appeals in *Sternberg v. Department of Health and Human Services* (No. 01-3185). **David Sternberg** defrauded Medicare in the 1990s by billing for services he never performed, double billing and up-coding; he was convicted on fraud charges in 1998. Part of a sentencing agreement between Sternberg and the feds said that upon release from five years incarceration, he would move for reinstatement to federal health care programs and agree to certain conditions relating to payment review and payment offsets.

After sentencing, however, the OIG imposed a 15-year exclusion on Sternberg — a move the psychiatrist argued breached the sentencing agreement because it would make it impossible for him to seek reinstatement after being freed from prison. In essence, Sternberg maintained that the settlement agreement not only permitted him to seek reinstatement on certain terms, it also compelled him to do so.

The 10th Circuit rejected that argument. "The agreement implicitly *conditions* Sternberg's obligation to move for reinstatement on his being allowed to do so," the court ruled. "If a condition does not or cannot occur then performance is not required." ❖

health plans would pay the fees for the program. Marketing and advertising by pharmacies and pharma companies would appear on the Web site.

The program is a classic disease management program in which a health plan identifies members with chronic conditions and then contracts with a DM company that then reminds those members to keep up with a regimen designed to maintain their health. Both members and physicians are awarded points for compliance that could be redeemable for goods and services that are not reimbursed by Medicare.

“Payments by the MCOs to the Requestor for the provision of behavior modification and drug compliance services should not implicate the anti-kickback statute because the services are not generally reimbursable under the Federal health care programs,” concludes the OIG. The “passive” nature of the Web advertising and the similarity between the pharma ads and permissible print ads allowed the OIG to give the green light to the advertising aspect of the program as well.

The agency is careful to limit the reach of the opinion to the parties at hand and expresses no opinion about whether the health plan’s initial gathering of the information to identify eligible members would violate privacy provisions of the Health Insurance Portability and Accountability Act. Go to <http://oig.hhs.gov/fraud/docs/advisoryopinions/2002/ao0212.pdf> to see the opinion. ❖

Liability

DRUG SWAPPING CAN LEAD TO MALPRACTICE LIABILITY

Health plans hoping to cut costs by switching prescriptions to generics should bear in mind that even the most expensive brand-name drug is less costly than a malpractice suit.

“There are some instances where, for some reason, a person does not react well to a certain generic drug,” warns malpractice attorney **Alan Duncan** with **Smith Moore** in Greensboro, NC. If a patient was switched to a generic and then had a bad reaction to the generic — or if it proved to be ineffective, as opposed to a brand name that would have done the trick — the patient could have grounds for a malpractice suit, Duncan says.

Though Duncan is not aware of any malpractice suits against MCOs or doctors for switching prescriptions to generics, he adds that he wouldn’t be surprised if there has indeed been such a suit.

Asked whether **Trigon Blue Cross Blue Shield** is concerned about potential liability issues, **Beth Laws**, a spokesperson for Trigon, notes that “generics are exactly the same — they do the same thing in your body as a brand name drug.” The only difference, she says, is “that billions of dollars haven’t been spent advertising them on the evening news.”

Nonetheless, medical science is a bit fuzzy when it comes to generics. “It’s not completely understood why” certain people respond differently to generics, explains **Geri Amori**, the past president of the **American Society of Risk Managers**.

Jeff Trewhitt, a spokesman for the **Pharmaceutical Research and Manufacturers of America**, says PhRMA has no objections to the process by which generics are tested and approved by the **Food and Drug Administration**. However, he does point out that it is less thorough than the process by which name brands are approved.

Trewhitt explains that though generics are “certainly very similar” to name brands, the FDA does allow for “a deviation of plus or minus 20 percent in bioequivalence,” meaning that some patients with delicate conditions might be affected differently by generics.

Though **Blue Cross Blue Shield of Illinois** is also preparing to encourage pharmacists to switch the generics, the company is concerned foremost with patients’ health and safety, says public affairs director **Bob Kieckhefer**. BCBSI merely wants to encourage each pharmacist to call the doctor and double-check that the doctor wants the brand-name instead of a cheaper generic. If the doctor says he still wants the brand name drug, then that’s what the patient gets, Kieckhefer says.

“We’re not trying to practice medicine or prescribe specific drugs or generic drugs, but we just want to make sure that the people that do that are doing it with an eye on costs,” he says.

Indeed, PhRMA’s one caveat, Trewhitt says, is that a doctor — and not a plan administrator — makes the final call on which drug to prescribe to which patient. “It is essential that the doctor who knows the patient best should make the final decision on which medicine to use,” he says. Because there are times when patients respond differently to generics, he argues, physicians need to be the ones who decide when a medication can be switched.

“It really needs to be a choice for the physician,” agrees Amori, currently an associate with **HCNA** in Lexington, MA. She thinks it would be fine for an MCO to “encourage” doctors to switch

to generics, but anything beyond encouragement would be pushing it.

Something as simple as appearances can also cause liability problems, Amori adds. "Part of the issue with generics is that they don't look like brand name drugs," she notes.

Amori knows of one case in which a pharmacy switched a patient's prescription from a brand name to a generic. The generic happened to look like one of the patient's other medications, so the patient got confused and wound up taking the wrong drug. ❖

Antitrust

AMA SICS FTC ON HEALTH PLANS

Like an angered athlete exhorting the referee to call fouls on both sides of the ball, the **American Medical Association** is hoping for equal enforcement of antitrust laws. Unfortunately for health plans, it may be getting its wish.

Alarmed by the recent spate of doctors and medical groups that have been investigated by the **Federal Trade Commission** for antitrust violations in dealing with health plans, the AMA is crying foul and demanding that the FTC turn its gaze to health plans.

At a Sept. 9 FTC antitrust conference, **Donald Palmisano**, president of the AMA, said "To our knowledge, the FTC has never brought a single enforcement action against a health insurance company, HMO, health plan or other third-party player."

Not for long. At the conference — which was also attended by representatives of the **American Association of Health Plans** — Deputy Assistant Attorney General **Deborah Majoras** said that investigators were looking into possible collusion between health insurers in one major U.S. city — but she would not say which, Reuters reports.

Majoras also noted that officials were following up on complaints from Philadelphia-area physicians who have accused local health plans of using contract language that gives the physicians worse reimbursement rates if they do not participate in all of the plans' services.

Palmisano notes that the late 1990s saw a consolidation binge in the health insurance industry as companies bought each other and merged "at a record pace." Because health premiums are now rising so soon after those consolidations and mergers, Palmisano says, the FTC should be sus-

picious that the mergers had anticompetitive effects on the market.

Palmisano reported that the AMA recently conducted a study of health plan consolidation across the country. "What we found was staggering," he said. "Out of 40 large metropolitan statistical areas ... approximately 70 percent of HMO markets were highly concentrated; 87.5 percent of PPO markets were highly concentrated; and nearly half of the combined HMO/PPO markets were highly concentrated."

"Moreover," it continues, "in roughly half of these highly concentrated MSA markets, a single payer had a market share in excess of 40 percent. And in a quarter of these markets, a single payer had a market share in excess of 50 percent."

The AMA is accusing the FTC of turning a blind eye to the health insurance industry. "In any other industry, a merger wave followed by an abrupt rise in prices would cry out for an investigation," Palmisano charges.

Representatives of the AAHP say they are not necessarily concerned about Palmisano's or the FTC's statements, and that this is just business as usual. ❖

Audits

MCO COMPLIANCE MEASURES WARD OFF INSTITUTIONAL STATUS ERRORS

King of Prussia, PA-based **Aetna U.S. Healthcare** has emerged relatively unscathed from an **HHS Office of Inspector General** review of how it handled Medicare payments for institutionalized enrollees.

Part of an ongoing nationwide series of managed care organization audits, the Aetna review chronicled in "Review of Medicare Payments for Beneficiaries with Institutional Status, Aetna U.S. Healthcare, King of Prussia, Pennsylvania" (A-05-01-00090) takes the measure of the MCO's compliance with the "institutionalized status" requirements laid out in operational policy letter 54. Those rules specify that a beneficiary must be a resident of a qualified facility for at least 30 days prior to the first day of a reporting month to qualify for enhanced payment.

In its review, the OIG did find some errors but noted that compliance measures implemented during the time period under scrutiny had almost completely eliminated any problems. Aetna's "current procedures were implemented in August 2000," the

OIG notes, “and we identified only one beneficiary incorrectly reported as institutionalized after the new verification process began.” ❖

Fraud & Abuse

TOP FRAUD FIGHTER TAKES NEW POST, EYES MANAGED CARE

A management reshuffling is changing the face of one of the most robust federal fraud fighting units in the country.

James Sheehan, long-time chief of the civil division at the U.S. attorney’s office in Philadelphia, has been promoted to the newly-minted post of associate U.S. attorney for civil programs, U.S. Attorney **Patrick Meehan** announced Sept. 13. Sheehan is one of the most distinguished health care fraud prosecutors in the nation, and a frequent speaker on fraud and abuse issues. He has personally handled or directly supervised more than 500 health care fraud cases.

Meehan says Sheehan’s new post “will allow us to work together even more closely, focusing on prescription drug benefits, predatory lending, quality of care in nursing homes and long-term care facilities, managed care, and other important initiatives.”

Taking Sheehan’s old job will be **Virginia Gibson**, former executive assistant U.S. attorney for the district of Delaware.

Sheehan’s new post appears to be designed to lighten his administrative load to free up more time for big-picture thinking. But whistleblower advocates are worried that the move could alter the enforcement climate. “To see him removed from his line authority is very depressing,” **James Moorman**, president of **Taxpayers Against Fraud** told the *Philadelphia Inquirer*. “This is going to make a lot of people nervous.” ❖

HIPAA

CMS TAKES NEW APPROACH TO SMALL HEALTH PLANS

The **Centers for Medicare & Medicaid Services** has issued more guidance on the vexing — and high-stakes — question of what it takes to qualify as a “small health plan” under the Health Insurance Portability and Accountability Act privacy regulation.

The guidance — part of the HIPAA fre-

quently asked questions section of its Web site — appears in a revamped response to the question “How should a health plan determine what receipts to use to decide whether it qualifies as a ‘small health plan.’” Plans that qualify as “small” get an extra year to comply with the privacy rule, making the question an extremely important one.

In the revised response, CMS notes that a “small health plan” is one whose annual receipts are \$5 million or less. The agency then cites guidelines promulgated by the **Small Business Administration** to clarify the complicated issue of what types of receipts should be counted toward the total.

The agency also provides new, albeit limited, HIPAA guidance in two newly added entries to the FAQ page. In the responses — posted Sept. 18 — the agency makes the following two points: First, “premiums or amounts paid for stop-loss insurance by an employer or sponsor of a self insured plan should not be included in the amount of receipts.”

Second, the SBA’s recent decision to define a small business as an organization that brings in less than \$6 million in receipts per year — rather than \$5 million, as was previously the case — has no effect on the HIPAA definition of a small health plan. A small health plan remains one whose receipts are less than \$5 million. ❖

Eli Research

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