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MEMORANDUM

TO: PCMA Board of Directors

FROM: Mark Merritt

RE: **PCMA's 6-Point Strategy to Engage the Trump Administration**

DATE: February 6, 2017

Executive Summary

PCMA is executing an aggressive strategy to engage the new Administration and counter efforts to undermine PBMs' ability to reduce costs for payers and consumers.

If this were a conventional Presidency, we'd wait to present a strategic update once key health officials were in place and new policy imperatives more clearly defined. We wanted to accelerate this review given the political uncertainty, headline risk, and other unique challenges that come with a President more inclined toward quick, instinctive action than the traditional, deliberative decision-making process.

As you know, PCMA has already presented a clear policy agenda to the transition team, launched a bold, new inside-the-Beltway [digital advertising campaign](#) to defend our value proposition, and implemented many other initiatives to strengthen our position in the Administration's first 100 days. But we need to do more to confront the unique challenges of this political environment.

To address this, PCMA is implementing a 6-point plan that includes:

1. Engaging key Administration officials on the PBM value proposition

2. PCMA's ongoing digital advertising campaign targeting policymakers
3. Building a political "firewall" on Capitol Hill
4. Exploring ways to leverage the 73,000 grassroots allies PCMA's recruited in key districts
5. Shaping the PBM regulatory environment
6. Mobilizing pro-payer allies and policy solutions

We will also work to arrange a Board call on PCMA's strategy and next steps as soon as possible.

Environmental Analysis

While a top health priority of the Administration and Congress has revolved around ACA, the President has made it clear that he wants to see drug companies reduce prices. Last week, drug company CEOs were called in by the President to address these concerns and the President subsequently outlined four priorities:

- Accelerate FDA approvals;
- Reduce prices through greater competition;
- Repatriate drug manufacturing jobs by removing regulatory barriers to building plants in the US; and
- End "global freeloading" where foreign countries pay less than Americans for drugs produced in the U.S.

While the President made no mention of "direct negotiation" or PBMs (in fact his HHS nominee highlighted the positive role of PBMs during his testimony) the manufacturers reportedly worked hard to convince him that the real cause of high

prices is a bloated supply chain. Whether the President was swayed by any of this is unclear.

Nevertheless, short-sellers and others have tried to capitalize on the general uncertainty surrounding drug issues. For example, they generated headline risk by claiming a recent CMS report on DIR in Medicare Part D means PBMs are “one Presidential tweet away” from disaster. Yet they failed to note that the report was issued on the last day of the Obama Administration, not by President Trump. The report also claims higher cost-sharing in Part D plans increases Medicare’s costs but then down plays the fact that those same plans’ lower premiums offer corresponding cost reductions.

In any case, the sense that this President could make any decision, at any time, for any reason, on any issue is rattling industries in the health care sector and beyond.

This makes it all the more urgent that we “cut through the clutter” and make our case as vocally and effectively as possible.

With that in mind, here is PCMA’s 6-point strategy for operating in this new environment.

#1: Target Key White House/Administration Leaders

PCMA is actively mapping and assessing the White House internal landscape to determine the different roles various staff will play on prescription drug issues. Several of these officials are in place and PCMA is working to set up meetings with them.

White House Meetings

- Domestic Policy Council, Healthcare Policy: **Katy Talento**
- The National Economic Council: **Brian Blase**, special assistant to the President
- The Vice President's health staffer, **Francis Brooke**

As we glean more intelligence from White House staff meetings, we'll assess the risks and benefits of a higher-level principals' meeting.

HHS and CMS Leadership Meetings

Given the President's repeated assurance that Secretary nominee Price will be involved in policies related to prescription drugs, we are working to get meetings with his advisers as soon as they are in place. After these discussions, we'll make a recommendation on when to engage the Secretary directly on our issues.

The CMS Administrator nominee and the HHS "beachhead" team have expressed interest in reassessing Medicaid formulary/rebate requirements and perhaps replacing them with some kind of Part D/private-sector-negotiated construct. PCMA is well positioned to help the agency on this as an outside, knowledgeable expert.

As key staff take office, PCMA will evaluate whether new outside consultants will be needed to help PCMA navigate the new Administration.

#2 PCMA's DrugBenefitSolutions.com Digital Ad Campaign

PCMA's aggressive new digital advertising platform—DrugBenefitSolutions.com—is promoting the industry's value proposition to the new administration, key policymakers, opinion leaders, allies and others.

It features videos, infographics, and other tools that offer simple explanations of drug pricing, rebates, transparency, and pro-PBM policy solutions that could reduce costs.

Since the ad blitz launched prior to the inauguration, the campaign is squarely in sync with the first 100 days of the new Administration. Attached is a campaign update and metrics report, similar to what was presented to the Operations Committee last week.

Meanwhile, in the last few weeks, PCMA's aggressive PR push has promoted and defended the industry in the following publications:

- *The New York Times*: [Specialty Pharmacies Say Benefit Managers Are Squeezing Them Out](#)
- *CBS Morning News*: [Mylan CEO on EpiPen drug price controversy: "I get the outrage"](#)

- *The Washington Post*: [Diabetes patients sue insulin makers for 'pricing fraud'](#)
- *American Pharmacy News*: [PBMs: Protecting Consumers and Employers From High Drug Prices](#)
- *Axios*: [The next drug pricing target: pharmacy benefit managers](#)
- *Inside Health Policy*: [Trump Calls For Lower Drug Prices, Medicare Bidding, Faster Approvals In Meeting With PhRMA](#)
- *Bloomberg*: [Iowa Drug-Pricing Law Struck Down by Appeals Court](#)
- *Politico*: [Cuomo's pharma proposals face uncertain future](#)
- *FiercePharma*: [New York takes drug pricing into its own hands with new clampdown](#)
- *Inside Health Policy*: [CMS: Current Rx-Price Rebates, Concessions May Not Benefit Consumers, Medicare](#)
- *Bloomberg*: [Growing Medicare Drug Fees Should Get Congress's Attention](#)
- *Bloomberg*: [Secret Rebates Erode Drugmaker Revenue, Industry Study Says](#)
- *Stat*: [Drug makers are sued for scheming to illegally fix insulin prices](#)
- *Inside Health Policy*: [Oncologists-Backed Paper Takes PBMs To Task Over Pharmacy Concessions](#)

Given the President's interest in a select number of news programs, PCMA will also explore other forms of advertising that target those particular venues.

#3: Build a Political Firewall on Capitol Hill

Despite the Administration's intent to change as much through regulation and executive order as possible, the role of Congress remains critical. We must guard against attempts to add anti-PBM provisions to "must-pass" legislation on ACA and FDA user fee reauthorizations.

PCMA is **targeting the four committees** (Senate, Finance, and HELP, House Energy and Commerce and Ways and Means) of jurisdiction for health care to educate them on drug pricing issues and share our agenda for the 115th Congress.

- PCMA is meeting this week with Energy and Commerce Chairman Greg Walden (R-OR) to discuss Medicare Part D, Medicaid, and FDA policy priorities. Chairman Walden was also involved in President Trump's meeting with the manufacturers and may be able to offer additional color on that meeting.
- PCMA is scheduling a meeting with Energy and Commerce Committee Health Subcommittee Chairman Dr. Michael Burgess (R-TX) and Ranking Member Frank Pallone (D-NJ).
- We're working on scheduling meetings with Ways and Means Chairman Kevin Brady (R-TX) and new Ranking Member Richard Neal (D-MA).
- PCMA is completing a round of meetings with the staff of each new member of the House Ways and Means (3 Republicans, 3 Democrats) and Energy and Commerce (4 Republicans, 3 Democrats) Committees, to discuss our legislative priorities and drug pricing issues.
- PCMA met with Congressman Peter Welch (D-VT), an ally of the independent drugstore lobby, to educate him about pharmacy issues from the PBM perspective and discuss drug pricing and how we can work together on affordability and coverage issues.
- PCMA also met with Rep. Larry Bouchon (R-IN), a thoracic surgeon and member of the E&C Health Subcommittee, who has manufacturer presence in his district and expressed repeated personal interest in addressing high-cost drug concerns.
- PCMA is requesting a meeting with Sen. John Barrasso (R-WY), an orthopedic surgeon and chairman of the Senate Republican Health Care Task Force and the Republican Policy Committee.
- Having met with all personal staffers of new Finance and HELP committee members, PCMA will be requesting additional meetings with the new senators over the next two months. PCMA also has met with the HELP and Finance Committee staffs.

#4: Digital Grassroots Targeting of Key Congressional Leaders

Since Q4, we have recruited nearly 50,000 new grassroots allies. Currently, our grassroots platform, the [Affordable Pharmacy Action Network, \(APAN\)](#) features more than 73,000 recruited allies who can be leveraged as needed to help drive our message in key districts around the country.

#5: Shaping the New PBM Regulatory Environment

PCMA has communicated with the Trump “beachhead team” members, who are managing agency activities as they await Congressional approval of the new HHS Secretary.

Since a key agency will be the Office of Management and Budget (OMB), we will work to set up a meeting with a new head of OIRA (once appointed), the OMB office that reviews the cost implications of all proposed rules prior to approval.

PCMA is updating all workgroups on the wide range of regulatory Executive Orders being issued by the new Administration, including orders on minimizing the burden of ACA, establishing a regulatory freeze, and establishing a “2 for 1” regulatory standard whereby for every new significant rule or guidance issued, two rules must be repealed. As we identify areas where regulations or guidance could be altered or withdrawn, our efforts will focus on using public comments and agency meetings (initially with the acting heads and then with new appointees as they arrive) to advance our goals.

We will request a meeting with incoming CMS Administrator Seema Varma as well as the appropriate deputies and heads of Medicare and Medicaid, once identified and hired, to brief them on industry proposals to address high-cost drugs in programs that CMS administers.

Specific PCMA workgroup activities include the following:

Medicare Part D Workgroup

- Developed detailed list of Part D regulatory provisions that need to be reassessed for possible repeal or revision by the new Administration. The list has been provided to the “beachhead team.”
- Included key points in comments for the draft 2018 Call Letter on Part D regulatory reform.
 - Assessed the impact of the recent CMS DIR report in the regulatory arena and are pleased to note that the draft 2018

Call Letter does not include any changes to the current regulatory landscape regarding DIR.

- Continuing to engage with a CMS task force on the prescriber enrollment policy, and we are optimistic that we are making progress in terms of fending off burdensome aspects of this agency effort.

Health Care Reform Workgroup

- Developed detailed list of ACA regulatory provisions that need to be reassessed for possible repeal or revision by the new Administration. The list has been provided to the “beachhead team.”
- Holding a seminar, by a consultant engaged with the transition/landing teams, to assess the impact of the new Executive Order on “Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal.”
- Tracking the development and release of a forthcoming “Mega-Reg” on health care reform, which is expected imminently.

Medicaid Workgroup

- Holding regular meetings in light of the significant attention now being focused on Medicaid, particularly with the CMS nominee, Seema Varma. She will, for the first time, bring in-depth Medicaid expertise to that role.
- Developed a detailed list of Medicaid managed care regulatory provisions that need to be reassessed for possible repeal or revision by the new Administration. This list has been provided to the “beachhead team.”
- Submitted a letter to the acting head of Medicaid (a career-staff holdover from the Obama Administration) officially asking for a delay in implementation for many provisions from the Medicaid managed care rule that have not yet taken effect. The letter has also been shared with the “beachhead team.”

Nondiscrimination Rule (Ad Hoc) Workgroup

- Presented on the nondiscrimination rule to the Administration transition team. After going as far as we could seeking relief from the prior Administration on the very burdensome and problematic notice and tagline provisions in the rule under ACA (often referred to as “Section 1557”), we presented the issue, along with possible resolutions, to the transition team. We are expecting regulatory relief, although we do not know in exactly what form or timing.
- Meeting with the Acting head of the Office of Civil Rights (a holdover from the Obama Administration) about ongoing 1557 concerns.

#6: Leveraging Pro-Payer Allies and Solutions

This week I'm meeting with AHIP President Marilyn Tavenner and her senior team to make sure the payer community is aligned and coordinated in its approach to the new Administration on prescription drug issues.

PCMA and other payer allies also work together on drug pricing issues through the Campaign for Sustainable Rx Pricing coalition whose members include BCBSA, AHIP, AARP, Walmart, and several PCMA member companies.

We are working primarily with payer groups since the traditional business trades are heavily conflicted by manufacturer and retailer membership. Employers could still be among our best allies, though, so we'll need your help to mobilize your employer clients to advocate on key prescription drug issues.

PCMA is also partnering with [The American Action Forum](#) (AAF) and others to highlight our pro-payer/pro-consumer messages.

AAF President (and former CBO director) Douglas Holtz-Eakin published a piece [following the drugmakers' White House meeting that noted:](#)

“Despite the repeated assertions to the contrary, there are tons of negotiations in the Medicare drug program. They are private negotiations between and among prescription drug plans, pharmacy benefit managers, and drug manufacturers — and they produce substantial price reductions. The government doesn't add anything to this mix because it doesn't have a formulary that would allow it to favor one drug over another, and negotiate a discount in exchange. The reality is that the federal government has no such mechanism to discriminate, and thus no real ability to more effectively negotiate.”

Americans for Tax Reform and the Citizens Against Government Waste [wrote a letter to Congress highlighting the success of Part D and how:](#)

“PBMs use a variety of methods, such as acquiring price concessions from both brand-name and generic drug manufacturers, rebates, and networks of more affordable pharmacies to lower drug costs for beneficiaries. PBMs also work with patients on drug adherence to keep them out of hospitals and doctors’ offices, which also helps to reduce healthcare costs.”

Policy Solutions for the New Administration

In preparation for the change in Administration, PCMA’s member companies agreed last year to pursue policies in five areas. These are:

- ***Increasing Competition to Address High-Drug Costs:*** We created a package of policy proposals to foster and increase competition among manufacturers in the prescription drug market and to bring value into negotiations. We will continue to show how competition—not government intervention—is the way to manage high-cost drugs.
- ***Promoting Greater Use of PBM tools in Part D:*** We enumerated a number of proposals to build on Part D’s private market structure by eliminating unnecessary hurdles to competition, such as removing protected classes and rolling back unnecessary coverage mandates. As Part D enters its second decade, it should remain the example of a well-run public-private partnership.
- ***Leveraging PBMs to Address the opioid crisis:*** The plague of opioid abuse was a top issue in the 2016 campaign cycle, especially given its human toll key, rural battleground states like Iowa and New Hampshire. PCMA formulated several proposals, such as mandating e-prescribing and improving state monitoring that would better leverage PBMs’ ability to detect inappropriate use, curb abuse and make diversion more difficult.
- ***Improving Drug Coverage in Exchange or successor plans:*** We have adopted a package of proposals to increase the value of drug benefits in plans on the Exchanges, or whatever type of drug coverage may take their place. We know that allowing PBMs to use techniques already working well in other areas of private coverage will be better for patients and generate savings.
- ***Increase the use of PBMs in Medicaid to reduce wasteful spending:*** PCMA is proposing new ways to allow PBMs to increase value and efficiency by bringing more proven benefit management tools to the Medicaid program. Policymakers welcome ways to generate efficiency and savings in any debate.

