

**TRANSITION MEMORANDUM FOR BIDEN ADMINISTRATION
DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS)
December 2020**

I. INTRODUCTION

The Center for Medicare Advocacy (the Center) looks forward to working with the Biden Administration’s Department of Health & Human Services. In this memorandum, we recommend a number of measures that the Department of Health and Human Services (HHS) and its Centers for Medicare & Medicaid Services (CMS) can take administratively to strengthen Medicare for beneficiaries. Part II of the Memo, the *Executive Summary*, summarizes the Center’s priorities for administrative measures that can and should be taken to improve Medicare. Part III – the Center’s *Medicare Platform* – provides a brief overview of the Center’s legislative priorities concerning Medicare, included here to provide a broader vision and context for our suggested administrative changes. Part IV – *Full Recommendations for Administrative Action* – details our recommended changes that can be achieved administratively, as summarized in the following *Executive Summary*.

II. EXECUTIVE SUMMARY: ADMINISTRATIVE MEASURES

Americans value Medicare. For decades it has added to the health and economic security of families nationwide. But Medicare needs attention to ensure all beneficiaries receive comprehensive coverage and equitable treatment. This is particularly true given the vulnerabilities of older people and people with disabilities, Medicare’s beneficiaries, as demonstrated by the COVID virus. Medicare improvements are necessary to successfully respond to the pandemic. It is time to build a better Medicare for all who rely on it now, and will in the future.

To strengthen and support Medicare, the Center for Medicare Advocacy recommends the following administrative actions that would improve access to coverage and quality care for all people who rely on Medicare. These recommendations do not require legislation. They are within the authority of the Department of Health and Human Services (DHHS) and the Centers for Medicare & Medicaid Services (CMS).

1. Strengthen Protections for Nursing Facility Residents

The Problem: The COVID pandemic has brought to public awareness the deadly consequences of the combination of poor care, inadequate staffing levels, insufficient

infection protections, and the systemic roll back of regulations intended to ensure good care for residents.

Administrative Action:

- Enforce infection control and other quality of care requirements to prevent diseases like Coronavirus from taking hold in skilled nursing facilities.
- Implement comprehensive staffing ratios to bring more qualified workers to care for our most vulnerable citizens.
- Expand training requirements to help upgrade skills and employment for aides and other direct care workers.
- Review and revise the Medicare payment model (Patient Driven Payment Model/ PDPM) and quality measure incentives to encourage access to appropriate staffing and all necessary, statutorily authorized care.

2. Redefine Inpatient Hospital Status – Increase Access to Necessary Care

The Problem: Currently, Medicare beneficiaries can spend many days in the hospital only to find they have been classified by the hospital as “outpatients,” and/or in observation status. As a consequence, they face barriers to Medicare-covered post-hospital nursing home care, which requires a prior inpatient hospital stay. An outpatient vs, inpatient label can also limit access to home health care given the incentives of the 2020 Medicare home health payment model. Further, since outpatient hospital care is covered by Medicare Part B, beneficiaries who only have Medicare Part A have no coverage at all for an outpatient/observation hospital stay.

Administrative Action:

- Revise all policies and regulations that define inpatient hospital care to include all care provided in the hospital, including Observation Status, when patients remain in the hospital for more than 24 hours.
- Exercise CMS’ authority under existing law to define hospital “inpatient” care to include all time spent in the hospital.
- Count all time spent in “outpatient” hospital observation status toward the prior inpatient hospitalization requirement for Medicare coverage of skilled nursing facility care.
- Consider patients who begin home health care after time spent in “outpatient” hospital/ observation status as inpatient admissions to home health care, not “community” admissions, as provided by the 2020 Medicare home health PDGM payment model.
- Rescind the *Outpatient Prospective Payment Surgical System (ASC) Final Rule* (12/2/2020) that will increase the pretense that patients cared for in hospitals are outpatients, effective January 1, 2021. By eliminating the “Hospital Inpatient Only List,” this new rule will dramatically increase hospitals classifying patients as outpatients, which creates significant barriers to post- hospital care, leaves patients who do not have Part B fully liable for their hospital care, and increases costs to Medicare Part B.

3. Ensure Access to Medicare-Covered Home Health Care

The Problem: COVID reminds us that most people want to remain home to receive needed care and that providing care at home is often safer for the patient and patient’s community. Unfortunately, Medicare beneficiaries are increasingly unable to obtain Medicare-covered home health care for which they are eligible under the law. This is particularly true for people with on-going conditions and care needs, and for those who need home health aide services. Ensuring access to home health should be considered as an essential component of the new administration’s work on Home and Community Based Services (HCBS).

Administrative Action:

- Enforce existing law to ensure access to all necessary Medicare-covered services for those who qualify under the law.
- Audit and monitor home health providers to ensure they have adequate staffing to provide, or arrange for, all Medicare-covered services.
- Audit and monitor the under-provision of necessary home health care, not just so-called “over-utilization” of care.
- Review and revise Medicare home health payment model (Patient Driven Grouping Model/ PDGM) and quality measure incentives, to encourage access to all necessary, statutorily authorized services, including home health aides.

4. Ensure Parity Between Traditional Medicare and Medicare Advantage and Promote Consumer Protections in Medicare Advantage

The Problem: The universal traditional Medicare program, preferred by most beneficiaries, has been neglected for years, while the private Medicare Advantage (MA) system has been repeatedly bolstered and promoted. This is leading to increased MA marketing and MA enrollment, even when it is not in the best interest of beneficiaries, Medicare, or taxpayers.

Administrative Action:

- Rebalance growing inequities between traditional Medicare and Medicare Advantage with regard to ease of enrollment, benefits, payments, and allocated resources.
- Address ongoing Medicare Advantage overpayments (and step up recoupment through Risk-Adjustment Data Validation program (RADV) audits).
- Enhance oversight and enforcement of MA plans (for example, regarding actual provision of coverage and care, and proper use of risk adjustments).
- Rescind recent updates to marketing and communications guidelines (MCMG) which, among other things, blurred distinctions between marketing and education.
- Eliminate bias towards Medicare Advantage plans in CMS materials, including outreach/enrollment materials, Medicare Plan Finder, *Medicare & You*, etc.

5. Actively Work to Enforce the *Jimmo v. Sebelius* Settlement – Require Fair Access to Coverage and Care for People with Chronic Conditions

The Problem: For too long, Medicare beneficiaries have been denied coverage and access to necessary care for which they qualify under the law, based on a long-standing myth that coverage is only available for people who will improve. In 2011 a nationwide class-action

lawsuit was brought on behalf of beneficiaries with longer term, debilitating, and chronic conditions to challenge these illegal denials. (*Jimmo v. Sebelius*, (D. Vt., 2013; 2017)) The *Jimmo* case was settled with CMS in 2013. The Settlement Agreement confirmed that **Medicare coverage is determined by a beneficiary's need for skilled care, not on a beneficiary's potential for improvement. Medicare coverage is available for skilled care to maintain or slow decline of an individual's condition. Improvement is not required.**

Unfortunately, many beneficiaries are still denied Medicare and access to necessary skilled care based on some variation of an "Improvement Standard." CMS is failing to ensure that the *Jimmo* Settlement Agreement is being properly implemented. The inadequate education of Medicare representatives, contractors, and providers about the Settlement results in continuing harm to Medicare beneficiaries in need of maintenance nursing and/or therapy services who are improperly denied access to appropriate Medicare coverage and care. Too often, when care is provided, the costs are inappropriately shifted to beneficiaries, families, and state Medicaid programs.

Administrative Action:

- Ensure CMS, its contractors, adjudicators, and providers are active partners in implementing the *Jimmo* Settlement.
- Require CMS to provide at least one training annually regarding the *Jimmo* Settlement for all contactors, adjudicators, and providers.
- Ensure Medicare providers know about the *Jimmo* Settlement, and provide appropriate access to coverage and care for people who need care to maintain their condition or slow decline, as authorized by law and confirmed by the court in *Jimmo v. Sebelius*.
- Monitor providers, contractors, and adjudicators at all levels of decision-making and appeals to ensure people who meet *Jimmo* criteria have appropriate access to coverage and care.
- Ensure CMS online and written materials and oral scripts recognize that Medicare can be available for necessary care to maintain an individual's condition or slow decline, and that improvement is not a prerequisite to coverage.

6. Cover Medically Necessary Oral Health Care

The Problem: Oral health/dental care is increasingly recognized as key to overall health. Unfortunately, CMS recognizes, but significantly limits, Medicare coverage for medically necessary oral health/dental services. While the Medicare Act excludes coverage for "routine" dental services, the exclusion should not be broadly construed to preclude coverage for oral health procedures in all circumstances; this was not the legislative intent. Medicare coverage for medically necessary oral health care is supported by the Medicare statute, its legislative history, CMS policy, and precedent established by Medicare coverage for podiatry services.

Administrative Action:

- Provide Medicare coverage for medically necessary oral health and dental services for conditions that pose a serious risk to a patient's health or medical treatment. This includes instances where a physician has determined that a patient's oral infection or disease will delay or prevent the receipt of, or otherwise complicate the outcome of, a Medicare-covered treatment for an underlying medical condition.
- Revise CMS policy to define coverage for medically necessary oral and dental therapies would not expand coverage beyond what the Medicare statute allows. To the contrary, it would uphold the general statutory exclusion of basic, routine dental care while fulfilling Congress' goal of ensuring access to and coverage of medically necessary treatment for major health problems.

7. Additional Areas of Concern

- Improve Part D Coverage and Appeals
- Address Flaws in the Medicare Appeals System
- Improve Access to Durable Medical Equipment (DME) for Dually Eligible Individuals
- Rescind Final Rule Rolling Back Critical Non-Discrimination Provisions Pursuant to §1557 of the Affordable Care Act
- Rescind the Public Charge Rule Which Creates Almost Insurmountable Barriers to Entry into the United States for Older Immigrants
- Withdraw/Rescind the Proposed SUNSET Rule that would put an Automatic Expiration Date on Critical Medicare (and Other) Regulations
- Suspend the Direct Contracting Demonstration that Leaves Critical Consumer Protection Issues Unaddressed
- Hold More Frequent Meetings with Advocates

III. MEDICARE PLATFORM: LEGISLATIVE AGENDA

Although this Memorandum focuses on suggested Medicare changes that can be achieved administratively, the Center for Medicare Advocacy also includes here our “Medicare Platform: Principles to Improve Medicare for All Beneficiaries Now and In the Future”¹ that contains both administrative and legislative improvements. This short list of principles addressing important enhancements to Medicare provides additional recommendations and context for the detailed administrative recommendations that follow.

1. Improve Consumer Protections and Quality Coverage

- Cap out-of-pocket costs in traditional Medicare²
- Require Medigap plans to be available to everyone in traditional Medicare, regardless of pre-existing conditions and age
- Ensure parity between Medicare Advantage (MA) and traditional Medicare
 - Ensure all benefits in Medicare Advantage are also available in traditional Medicare, such as the waiver of 3-day prior hospital stay requirement for skilled nursing home care, coverage for home health aides, certain oral health, vision, and audiology services
 - Ensure payment in traditional Medicare is at least as much per enrollee as in Medicare Advantage³
- Simplify enrollment in traditional Medicare, Part D and Medigap, and ease transitions from other insurances to Medicare
- Improve consumer protections in Medicare Advantage
 - Standardize benefit packages⁴
 - Strengthen plan oversight, including ensuring plans contract with enough providers who are accessible to plan enrollees (network adequacy)⁵
 - Strengthen marketing protections⁶
- Ensure parity between mental health and physical health coverage
- Ensure the Medicare appeals system is cost-effective and fair for beneficiaries
 - Ensure access to timely, meaningful decision-making, and written determinations at all levels of appeal

¹ The Center for Medicare Advocacy’s “Medicare Platform: Principles to Improve Medicare for All Beneficiaries Now and In the Future” is also available online at: <https://medicareadvocacy.org/medicare-info/medicare-and-health-care-reform/#medicare-platform-principles-to-improve-medicare-for-all-beneficiaries-now-and-in-the-future>.

² In 2016, the average person with Medicare coverage spent \$5,460 out of their own pocket for health care ([Kaiser Family Foundation](#), 2019).

³ On average, MA plans are still being overpaid due, in part, to manipulation of risk adjusted payment and a broken quality bonus payment system; see, e.g., <https://medicareadvocacy.org/medicare-advantage-continues-to-drive-up-medicare-costs>, <https://medicareadvocacy.org/support-traditional-medicare-by-leveling-the-playing-field-with-medicare-advantage/>, http://www.medpac.gov/docs/default-source/reports/jun19_ch8_medpac_reporttocongress_sec.pdf.

⁴ See, e.g., <https://medicareadvocacy.org/center-comments-on-medicare-advantage-and-part-d-transformation-ideas/>.

⁵ See, e.g., discussion of reversing MA network adequacy changes in recent final Part C & D rule at: <https://medicareadvocacy.org/final-rule-for-medicare-parts-c-and-d-includes-weakened-standards-for-medicare-advantage-networks/>.

⁶ See, comments to proposed Part C & D rule at: <https://medicareadvocacy.org/wp-content/uploads/2020/04/CMA-CD-Comments-2020.pdf>.

- Add a meaningful appeals process for hospice coverage⁷

2. Reduce Ongoing Barriers to Care

- Eliminate the harm of so-called hospital “Observation Status” when a person is actually in the hospital
 - Eliminate the 3-day prior inpatient hospitalization requirement for skilled nursing facility coverage or, at least, count all time in the hospital towards the 3-day prior hospital requirement
- Ensure access to home health coverage is actually available for all beneficiaries who meet coverage criteria; ensure access to legally authorized home health aides; resolve conflicts between payment models and coverage laws⁸
- Ensure access to quality skilled nursing facility care
 - Require adequate staffing ratios, provider payments subject to a medical loss ratio, and adequate oversight and enforcement
- Ensure beneficiaries with longer-term, chronic, and/or debilitating conditions have full access to skilled nursing, therapy and related care needed to maintain their conditions or slow decline, as is required by law

3. Improve Traditional Medicare

- Ensure traditional Medicare is comprehensive, simple to navigate, and affordable
- Add oral health, audiology, and vision coverage for all beneficiaries in traditional Medicare
- Increase low-income protections and reduce cost-sharing
- Add coverage for long-term care
- As in HR 3,⁹ ensure savings achieved through drug negotiations, or by other means, are reinvested into the Medicare program

**Improve and simplify Medicare. Don’t privatize or cut it.
Build it better. Then expand access for generations to come.**

⁷ For example, establish an expedited appeals process for hospice coverage issues similar to one currently in regulations for untimely discharges from skilled nursing facilities, home health and hospice – see 42 CFR §405.1200, et seq.

⁸ For example, consider lifting or expanding the current statutory cap on outlier payments (claimed for individuals with significant resource needs) from 2.5% of total Medicare home health payments, and 10% of expenditures to any singular home health agency. These caps inappropriately limit access to necessary services under the guise of controlling fraud.

⁹ H.R.3 – Elijah E. Cummings Lower Drug Costs Now Act (passed House of Representatives 12/12/19).

IV. ADMINISTRATIVE ACTION: FULL RECOMMENDATIONS

The Center for Medicare Advocacy (the Center) submits the following proposals regarding the Medicare program that are within the authority of the Department of Health and Human Services (DHHS) and the Centers for Medicare & Medicaid Services (CMS). These proposals do not require additional legislation to implement and would improve Medicare beneficiaries' access to coverage and quality care.

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 - f. Withdraw/Rescind SUNSET Proposed Rule that would put an Automatic Expiration Date on Critical Medicare (and Other) Regulations
 - g. Suspend Direct Contracting Demonstration
 - h. Hold More Frequent Meetings with Advocates

1. **Strengthen Protections for Nursing Facility Residents**

The Problem: The COVID pandemic has brought to public awareness the deadly consequences of the combination of poor care, inadequate staffing levels, insufficient infection protections, and the systemic roll back of regulations intended to ensure good care for residents.

The COVID-19 pandemic has brought to fuller public awareness the deadly consequences of poor care, inadequate staffing levels, racial disparities, and the deregulation of essential regulations intended to ensure good care for nursing facility residents. Although many of the problems in nursing facilities have been identified for decades, they have been made worse by the Trump Administration’s deregulatory actions and the coronavirus pandemic. This administration treated these essential regulations as nothing more than a burden on nursing facilities that must be eliminated in order to protect the facility. Essential changes are needed. While some issues can only be addressed through legislation, much can be done administratively, including reinstating many of the resident protections that existed prior to the Trump Administration and those that the Administration has expressly waived since the beginning of the pandemic.

As documented by the Center for Medicare Advocacy in testimony before the House Ways & Means Committee in June 2020,¹⁰ during the coronavirus pandemic and national health emergency, the Trump Administration unilaterally decimated longstanding statutory and regulatory protections for residents. Through the “COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers,”¹¹ originally issued in March 2020 and updated periodically since, CMS has waived multiple longstanding resident protections, including visitation, transfer and discharge rules, resident groups, and training requirements for nurse aides and paid feeding assistants, as well as rules governing physical environment (which buildings can be used to provide care to residents) and facility reporting (resident assessment information, staffing information [since reinstated, effective the second quarter of 2020]). Waivers issued during the health care emergency cannot be allowed to continue indefinitely. They have not kept residents safe and have allowed nursing facilities to hide information documenting resident decline and neglect.

The most vivid example of a waiver that needs to be revoked is CMS’s barring virtually all visitors to nursing homes since March 2020. While the policy may have been understandable at the beginning of the pandemic, it has not kept COVID-19 out of facilities. Asymptomatic staff and symptomatic staff continuing to go to work in the facilities because they cannot afford to miss a paycheck have continued, inadvertently, to spread COVID-19 to residents and other staff. Moreover, before the pandemic, many family members provided direct care to residents on a regular basis, supplementing staff by feeding their relatives and performing other essential tasks. Denying residents any visitors since March, except under the most limited circumstances, has deprived residents of that care. The absence of visitors has also led to psychological harm, isolation and depression, and deaths from “failure to thrive.”

CMS liberalized visitation policies in September,¹² but many states and facilities have ignored the guidance and continued to deny all or most visitation. CMS must end the waiver that

¹⁰ House Ways & Means Health Subcommittee hearing entitled “[Examining the COVID-19 Nursing Home Crisis](#)” on June 25, 2020 – see written [testimony](#) of Center for Medicare Advocacy Senior Policy Attorney Toby Edelman.

¹¹ CMS document: <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>, (Sep. 29, 2020 update).

¹² CMS, “Nursing Home Visitation – COVID-19,” QSO-20-39-NH (Sep. 17, 2020), [Nursing Home Visitation- COVID-19 \(cms.gov\)](#).

prohibits visits and reinstate rules, not just guidance, that ensures residents can have **safe** visits with family and friends.

In March 2020, CMS waived transfer and discharge protections for the sole purpose of allowing facilities to cohort residents with similar COVID-19 status. Despite the very limited waiver, facilities have exploited the waiver and absence of public oversight (see discussion below) to illegally discharge residents to homeless shelters¹³ and mental health facilities,¹⁴ without consequence or sanction. CMS must revoke the waiver and make clear that illegal transfers and discharges will not be tolerated.

CMS needs to reinstate all of the waived resident protections as quickly as possible.

In March, CMS waived various facility reporting requirements. It waived the requirement that facilities report staffing through the Payroll-Based Journal System. In June, CMS ended the waiver and reinstated the requirement for staff reporting, beginning with the second calendar quarter of 2020 (April-June 2020).¹⁵ In March, CMS also waived a requirement that facilities report resident assessment data (known as the minimum data set, MDS). MDS data are used to develop both residents' care plans and publicly reported Quality Measures on the federal website *Nursing Home Compare*, now merged into *Care Compare*. CMS reported in December that most facilities had continued to report MDS data during the pandemic and that it would use those data, beginning January 27, 2021, to update the federal website.¹⁶ The Center urges CMS to require facilities to comply with all reporting requirements, retroactive to January 2020. Such comprehensive reporting is needed in order to create a true and complete understanding of how facilities were staffed and how facilities assessed residents during the pandemic.

Another March 2020 waiver allowed nursing facilities to employ direct care workers who did not meet their state's nurse aide training and competency evaluation requirements. The nursing home trade association American Health Care Association created a free eight-hour online training program, which multiple states explicitly adopted.¹⁷

CMS must revoke the waiver and require that aides and feeding assistants hired under minimal training requirements during the pandemic take their state's full training course and pass the state's competency evaluation test in order to continue working, after a CMS-designated period

¹³ Jessica Silver-Greenberg and Amy Julia Harris, "'They Just Dumped Him Like Trash': Nursing Homes Evict Vulnerable Residents," *The New York Times* (Jul. 23, 2020), <https://www.nytimes.com/2020/06/21/business/nursing-homes-evictions-discharges-coronavirus.html?searchResultPosition=14>.

¹⁴ Jessica Silver-Greenberg and Rachel Abrams, "Nursing Homes Oust Unwanted Patients With Claims of Psychosis," *The New York Times* (Sep. 19, 2020), <https://www.nytimes.com/2020/09/19/business/coronavirus-nursing-homes.html?searchResultPosition=1>.

¹⁵ CMS, "Changes to Staffing Information and Quality Measures Posted on the Nursing Home Compare Website and Five Star Quality Rating System due to the COVID-19 Public Health Emergency," QSO 20-34-NH (Jun. 25, 2020), <https://www.cms.gov/files/document/qso-20-34-nh.pdf>.

¹⁶ CMS, "Updates to the Nursing Home Compare website and Five Star Quality Rating System," QSO 21-06-NH (Dec. 4, 2020), <https://www.cms.gov/files/document/qso-21-06-nh.pdf>.

¹⁷ Center for Medicare Advocacy, "Who's Providing Care to Nursing Home Residents?" (CMA Alert, Jul, 29, 2020), <https://medicareadvocacy.org/whos-providing-care-to-nursing-home-residents/>; full report, <https://medicareadvocacy.org/wp-content/uploads/2020/07/Report-Nurse-Aide-Training.pdf>.

of time.¹⁸ CMS must expressly confirm that “grandfathering” minimally trained aides and feeding assistants is not permissible. Waiving nursing staff training requirements has the effect of permanently degrading staff positions and undermining the 1987 law’s explicit mandate to strengthen and improve staffing standards. Studies of staffing levels during the pandemic document that better-staffed facilities have fewer COVID-19 cases and deaths.¹⁹

CMS should also reverse its policy, disclosed to residents’ advocates during a telephone call in the summer, that it could not revise the PBJ reporting system to account for temporary nurse aides and that facilities could report these minimally trained workers to CMS as if they were fully trained and certified nurse assistants. CMS then reports these workers to the public on *Care Compare* as fully trained aides. CMS must reverse this policy and ensure that facilities report to CMS, and CMS publicly and separately discloses, the categories of certified nurse aides and (until the position is eliminated) temporary nurse aides. Accurate reporting of staffing must be retroactive to March 2020.

Strengthen the Survey and Enforcement Systems

The public oversight system, set out in the 1987 Nursing Home Reform Law, is based on surveys by state agencies, using survey protocols developed and issued by CMS, and enforcement (defined as a range of financial and non-financial penalties for deficiencies). Even before the pandemic, the Trump Administration undermined and took multiple steps to dismantle this oversight system, primarily through sub-regulatory guidance that it issued unilaterally and without notice and public comment – memoranda addressed to State survey agencies and the civil money penalty analytic tool. The most visible change was making per instance civil money penalties (CMPs) the default fine, reversing the Obama Administration’s analytic tool that made per day CMPs the default.²⁰ The result of the multiple sub-regulatory changes made by the Administration was the imposition of minimal fines, if any, for even the most serious care problems.

During the coronavirus pandemic and national health emergency, the Trump Administration further degraded the public oversight system by suspending surveys and enforcement for all but the most egregious violations and a new type of survey focused solely on infection prevention

¹⁸ In an October 30, 2020 letter, Congressman Lloyd Doggett (D, TX) and colleagues asked CMS to promptly reinstate nurse aide training requirements that have been suspended since March 2020; to gather, and make publicly available, information about temporary nurse aides with minimal training who have been working in facilities during the pandemic; and to ensure that temporary aides fully meet federal and state training requirements. https://doggett.house.gov/sites/doggett.house.gov/files/CMS_Nurse%20Aide%20Training%20Letter%2010%2030%2020_Signed.pdf.

¹⁹ Center for Medicare Advocacy, “Studies Find Higher Nurse Staffing Levels in Nursing Facilities Are Correlated With Better Containment Of COVID-19” (CMA Alert, Aug. 13, 2020), <https://medicareadvocacy.org/studies-find-higher-nurse-staffing-levels-in-nursing-facilities-are-correlated-with-better-containment-of-covid-19/> (discussing four recent studies, using different databases, criteria, dates, and states, that all confirm that nursing facilities with more nurses are more successful in containing coronavirus cases and deaths among residents than facilities with lower nurse staffing levels).

²⁰ Toby S. Edelman, “Deregulating Nursing Homes,” *Bifocal*, Vol. 39, Issue 3 (Jan. 2018), https://www.americanbar.org/groups/law_aging/publications/bifocal/vol--39/issue-3--february-2018-/DeregulatingNursingHomes/.

and control requirements.²¹ Focused infection control surveys have cited few deficiencies and classified most of them as causing “no harm” to residents, a category in the federal enforcement system that rarely leads to any financial penalty.²²

CMS has slowly sought to expand survey activities and to reinstate the regular survey process (unannounced annual and complaint surveys) that determines compliance with the full range of federal requirements for care.²³ However, any expansion depends on COVID-19 rates in the community and the availability of personal protective equipment for survey staff. Most states have conducted few, if any, standard surveys since the CMS announcement.

The Center supports reinstatement of the comprehensive standard survey and complaint process as quickly as possible, and, in the meantime, an expansion of any survey to include essential attention to quality of care and quality of life issues for residents. Surveyors cannot continue to limit surveys to infection control and ignore significant care issues. Whenever surveyors are present in a facility, they must determine whether residents are receiving the essential care they need.

Restoring the prior survey and enforcement systems, while necessary, is not sufficient. Over the decades, the Government Accountability Office (GAO) and the Office of Inspector General (OIG) and others have issued multiple reports documenting that the public oversight system has failed to ensure that facilities fully meet federal standards of care. Here are just a few of the more recent reports:

- GAO, *Infection Control Deficiencies Were Widespread and Persistent in Nursing Homes Prior to COVID-19 Pandemic*, GAO-20-576R (May 20, 2020), *Deficiencies Were Widespread and Persistent in Nursing Homes Prior to COVID-19 Pandemic*, <https://www.gao.gov/assets/710/707069.pdf> (documenting 82% of facilities cited with infection control deficiencies, 2013-2017; 48% cited in multiple years; 99+% of the deficiencies did not result in any financial penalty); and
- GAO, *Nursing Homes: Improved Oversight Needed to Better Protect Residents from Abuse*, GAO-19-433 (Jun. 2019), <https://www.gao.gov/assets/700/699721.pdf> (reporting more than a doubling of abuse deficiencies between 2013 and 2017, with the largest increase in actual harm or immediate jeopardy; most abuse deficiencies cited as a result of a complaint survey or facility-reported incident; multiple facilities were cited with

²¹ CMS, “Suspension of Survey Activities,” QSO-20-12-All (Mar. 4, 2020), <https://www.cms.gov/files/document/qso-20-12-all.pdf>; CMS, “Prioritization of Survey Activities,” QSO-20-20-All (Mar. 20, 2020), <https://www.cms.gov/files/document/qso-20-20-allpdf.pdf-0>.

²² The Center has analyzed these focused infection control surveys and issued monthly reports about them. See, for example, “Infection Control Surveys In Nursing Facilities: As Deaths Soar, CMS Reports Few Deficiencies, Primarily ‘No Harm’” (CMA Alert, Nov. 12, 2020), <https://medicareadvocacy.org/infection-control-surveys-in-nursing-facilities-as-deaths-soar-cms-reports-few-deficiencies-primarily-no-harm/>.

²³ CMS, “COVID-19 Survey Activities, CARES Act Funding, Enhanced Enforcement for Infection Control deficiencies, and Quality Improvement Activities in Nursing Homes,” QSO-20-31-ALL (Jun. 1, 2020), <https://www.cms.gov/files/document/qso-20-31-all.pdf>; CMS, “Enforcement Cases Held during the Prioritization Period and Revised Survey Prioritization,” QSO-20-35-ALL (Aug. 17, 2020), <https://www.cms.gov/files/document/qso-20-35-all.pdf>.

multiple abuse deficiencies; less than 8% of abuse deficiencies had any enforcement action imposed).

- *OIG, Some Nursing Homes' Reported Staffing Levels in 2018 Raise Concerns; Consumer Transparency Could Be Increased*, OEI-04-18-00450 (Aug. 2020), <https://oig.hhs.gov/oei/reports/OEI-04-18-00450.pdf> (finding 943 nursing facilities (7%) failed to meet nurse staffing levels for at least 30 days in 2018, including failure to have a registered nurse present at least eight hours per day, as required by federal law, for an average of 58 days);
- *OIG, Incidents of Potential Abuse and Neglect at Skilled Nursing Facilities Were Not Always Reported and Investigated*, A-01-16-00509 (Jun. 2019), <https://oig.hhs.gov/oas/reports/region1/11600509.pdf> (reporting that one in five incidents for certain diagnoses, as documented in hospital emergency room Medicare claims, reflected potential abuse, neglect, or injury of unknown origin, but skilled nursing facilities failed to report 84% of the incidents to the state survey agency, as required);
- *OIG, Trends in Deficiencies at Nursing Homes Show That Improvements Are Needed To Ensure the Health and Safety of Residents*, A-09-18-02010 (Apr. 2019), <https://www.oig.hhs.gov/oas/reports/region9/91802010.asp> (analyzing 346,000 surveys citing 571,1000 deficiencies (D or higher); finds 94% cited as no-harm; 59% of serious deficiencies cited as result of complaint surveys); and
- *OIG, Adverse Events in Skilled Nursing Facilities: National Incidence among Medicare Beneficiaries*, OEI-06-11-00370 (Feb. 2014), <https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf> (finding a third of Medicare beneficiaries experience an adverse event or other harm, most of which was preventable, within 15.5 days of admission to a Medicare-covered stay).

The public oversight system needs to be significantly strengthened to include some fundamental changes: both greater scrutiny of who is allowed to own, operate, and manage nursing homes and receive reimbursement from the Medicare and Medicaid programs as well as greater accountability for public funding (including a direct care ratio limiting use of reimbursement for overhead, administration, and profit). These broader changes require legislative or regulatory change. However, it is possible that some intermediate steps, such as requiring facilities to submit consolidated financial statements, audited by a certified public accountant, and requiring CMS to audit at least a sample facilities' cost reports and financial statements, may be administratively established.

Protect Nursing Facility Residents from the Inappropriate Prescribing of Antipsychotic Drugs

While the Center for Medicare Advocacy generally opposes the application of utilization management controls for drugs within protected classes under Part D of Medicare, we support the use of some utilization management within protected classes in the long-term care setting, where antipsychotic drugs are frequently inappropriately prescribed.²⁴

²⁴ See, e.g., Center Comments on Medicare Advantage and Part D "Transformation Ideas" (April 2017), available at: <https://www.medicareadvocacy.org/center-comments-on-medicare-advantage-and-part-d-transformation-ideas/>; these comments were adapted from the Center's Comments to Notice of Proposed Rule Making (NPRM)

While the Center supports the current rules surrounding protected categories of drugs under Medicare Part D, we have significant concerns about the inappropriate prescribing of antipsychotic drugs in the long-term care setting and urge CMS to impose stronger requirements on Part D plans to protect such individuals. Whether or not antipsychotic drugs remain a protected class for Medicare beneficiaries who have a medical need for such drugs is a separate issue from the need to protect nursing home residents from the inappropriate prescribing of antipsychotic drugs. Establishing long overdue protections for residents does not depend on changing the rules for antipsychotic drugs for people for whom they are medically necessary.

There is no question that antipsychotic drugs are medically inappropriate for the vast majority of nursing home residents for whom they are prescribed. The Inspector General conclusively documented in 2011 that hundreds of thousands of residents received antipsychotic drugs and that 83% of the claims were for off-label conditions, including 88% for conditions specified in the black-box warning given to antipsychotic drugs by the Food and Drug Administration (FDA).²⁵ The American Geriatric Society's Beers List of drugs that are inappropriate for older people includes antipsychotic drugs.²⁶ The Senate Special Committee on Aging held a hearing in 2011 on the misuse of antipsychotic drugs in nursing homes, *Overprescribed: The Human and Taxpayers' Costs of Antipsychotics in Nursing Homes* (Nov. 30, 2011).²⁷

CMS is aware of the problem of the pervasive misuse of antipsychotic drugs in nursing homes and already has the tools to address it. CMS expressed concern in a 2014 proposed rule, which was never made final, that the use of antipsychotic drugs for nursing home residents "is, in many cases, unwarranted and in others, possibly dangerous."²⁸ CMS also recognized in the proposed rule that "Coverage under Part D is not available for drugs that are not used for a medically-accepted indication" and that "Prior authorization requirements to determine medically-accepted indications should be limited to those drugs for which it is reasonably foreseeable that use for non-medically-accepted indications are likely to occur."²⁹ CMS must apply its knowledge and these principles to protect residents.

We urge that Part D rules be amended to:

- Require plans to implement prior authorization rules for antipsychotic drugs for nursing home residents. Plans know which plan participants are in nursing homes.

CMS- 4159-P (March 7, 2014), available at: <https://www.medicareadvocacy.org/center-comments-on-proposed-medicare-part-c-part-d-rules/>.

²⁵ Office of Inspector General, Department of Health and Human Services, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, OEI-07-08-00150 (May 2011), <http://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>. (The report understates the use of antipsychotic drugs in nursing homes because it did not address the use of conventional antipsychotic drugs, which are also subject to an FDA black box warning.)

²⁶ American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults, *Journal of the American Geriatrics Society*, JAGS 00:1–21, 2019, <http://www.xayxfw.com/uploadfiles/2019/02/20190215084006406.pdf>.

²⁷ See <http://www.aging.senate.gov/hearings/overprescribed-the-human-and-taxpayers-costs-of-antipsychotics-in-nursing-homes>.

²⁸ 79 Fed. Reg. 1917, 1945 (Jan. 10, 2014).

²⁹ 79 Fed. Reg. 1943.

- Require plans to implement medication therapy management for all nursing home residents who receive antipsychotic drugs.

CMS must use current rules to protect residents in a Part A Medicare stay, whose drugs are covered by Part A.

Revise Nursing Facility Payment to Incentivize Necessary Care

On October 1, 2019, CMS began implementing the Patient Driven Payment Model (PDPM) for Medicare-covered skilled nursing facility care. Most notably, under PDPM, skilled nursing facilities have a greater financial incentive to provide little to no therapy to beneficiaries.³⁰ Furthermore, PDPM allows skilled nursing facilities to provide 25 percent of a resident’s total therapy regimen, by discipline, in group and concurrent therapy settings; there is no penalty for exceeding this limit. As a result, PDPM incentivizes skilled nursing facilities to provide not only less therapy overall but also less individualized therapy in particular. Within days of PDPM’s implementation, stories began to verify concerns about the payment model. For example, *Modern Healthcare* reported “[s]killed-nursing chains have terminated or ‘transitioned’ many of their therapists. Those who remain have been asked to boost their productivity and quickly cycle through patients as well as increase their use of group and concurrent therapy rather than one-on-one sessions.” PDPM also encourages shorter lengths of stay than the 100 days that the Medicare program authorizes by automatically reducing payments, on a sliding scale, during a resident’s Part A stay, regardless of the resident’s continuing need for skilled nursing care and skilled therapy services.

For many years, through payment and quality rules, CMS has been moving Medicare benefits toward shorter-term coverage, despite Medicare coverage laws that provide for individuals with longer term and chronic conditions. These new payment rules will accelerate the discrepancy between services Medicare legally covers and services that beneficiaries are actually able to obtain. We urge CMS to revisit these payment rules in order to incentivize SNFs to offer the full range of medically necessary care covered by Medicare.

2. Redefine Inpatient Hospital Status – Increase Access to Necessary Care

The Problem: Currently, Medicare beneficiaries can spend many days in the hospital only to find they have been classified by the hospital as “outpatients,” and/or in observation status. As a consequence, they face barriers to Medicare-covered post-hospital nursing home care, which requires a prior inpatient hospital stay. An outpatient vs, inpatient label can also limit access to home health care given the incentives of the 2020 Medicare home health payment model. Further, since outpatient hospital care is covered by Medicare Part B, beneficiaries who only have Medicare Part A have no coverage at all for an outpatient/observation hospital stay.

³⁰ For an analysis of the impact on PDPM on SNF coverage incentives, see, e.g., Center for Medicare Advocacy (October 2019) at: <https://medicareadvocacy.org/potential-impacts-of-new-medicare-payment-models-on-skilled-nursing-facility-and-home-health-care/>.

CMS has Authority under Existing Law to Define “Inpatient” Hospital Care – Time Spent in Observation Status Should Therefore Be Deemed to Count Toward the Prior Hospitalization Requirement for Skilled Nursing Facility Care

When hospital patients are classified as outpatients on Observation Status, they may be charged for services that Medicare would have paid if they were formally admitted as inpatients. For example, patients may be charged for their medications. (Thus, people may want to bring their medications from home if they go to the hospital.) Most significantly, patients will not be able to obtain any Medicare coverage if they need skilled nursing facility care after their hospital stay. Medicare only covers nursing home care for patients who have a 3-day inpatient hospital stay – Observation Status, as an outpatient classification, doesn’t count towards the 3-day stay. CMS, however, has the authority to change this interpretation through sub-regulatory guidance.

As the Second Circuit Court of Appeals ruled in 2008, the Secretary of HHS has authority under the Medicare statute to include a hospital patient’s time in observation as part of inpatient time in the hospital for purposes of determining whether the patient qualifies for Part A coverage of a subsequent stay in a skilled nursing facility (SNF).³¹ The Court recognized that neither the statute nor regulations define the word “inpatient” and that the Secretary defined inpatient in the Medicare Benefit Policy Manual as occurring after a formal physician order for admission. Although the Court upheld the Secretary’s position in litigation – that only time in formal inpatient status may be counted toward satisfying the qualifying three-day inpatient requirement – it also acknowledged that the Secretary had authority to *change* his interpretation of inpatient to include time spent in observation. The Court wrote:

[W]e note that the Medicare statute does not unambiguously require the construction we have adopted. If CMS were to promulgate a different definition of inpatient in the exercise of its authority to make rules carrying the force of law, that definition would be eligible for Chevron deference notwithstanding our holding today. 545 F.3d at 112.

In fact, the Centers for Medicare & Medicaid Services (CMS) has recognized its authority to change the definition of inpatient. In May 2005, CMS asked for public comment on whether time in observation should be counted towards satisfying the three-day inpatient requirement for Medicare Part A SNF coverage.³² In August 2005, CMS acknowledged that most commenters “expressed support for the idea that hospital time spent in observation status immediately preceding a formal inpatient admission should count toward satisfying the SNF benefit’s statutory qualifying three-day hospital stay requirement.”³³ CMS reported that “some advocated eliminating the statutory requirement altogether.”³⁴

CMS analyzed the two suggestions separately. With respect to repealing the three-day requirement entirely, CMS wrote, “we note that such an action would require legislation by the Congress to amend the law itself and, thus, is beyond the scope of this final rule.”³⁵ With respect to *counting* time in observation towards the qualifying inpatient stay, CMS wrote, “we note that

³¹ *Estate of Landers v. Leavitt*, 545 F.3d 98 (2nd Cir. 2008).

³² 70 Fed. Reg. 29069, 29098-29100 (May 19, 2005).

³³ 70 Fed. Reg. 45025, 45050 (Aug. 4, 2005).

³⁴ *Id.*

³⁵ *Id.*

we are continuing to review this issue, but are not yet ready to make a final determination at this time.”³⁶

CMS correctly understood that it could not repeal the three-day statutory requirement by regulation but that it *could* count the time in outpatient status, if it chose. Its only stated reason for not counting observation time, despite widespread support of such a change from commenters, was that it wanted to continue reviewing the issue.

Finally, CMS allows certain hospital stays to count in qualifying a patient for Part A-covered SNF care even when the hospital care is different from Part A-covered hospital care.

In the context of hospice services, CMS has recognized that “general inpatient care” in a hospital, although “not equivalent to a hospital level of care under the Medicare hospital benefit,” nevertheless qualifies a hospice beneficiary for Part A-covered SNF services.³⁷

Similarly, a three-day stay in a foreign hospital may qualify a beneficiary for Part A SNF coverage if the foreign hospital is qualified as an “emergency hospital.”³⁸

The argument for counting observation or outpatient time for purposes of calculating eligibility for the Part A SNF benefit is, of course, far stronger than either of the prior examples since the consensus is that care in the hospital is indistinguishable whether the patient is formally admitted as an inpatient or called an outpatient.

Most recently, in describing why a beneficiary continues to be eligible for Part A SNF coverage after the hospital withdraws its Part A claim and submits Part B claims for the patient’s care instead (the hospital rebilling option), CMS writes, “the 3-day inpatient hospital stay which qualifies a beneficiary for ‘post hospital’ SNF benefits need not actually be Medicare-covered, as long as it is medically necessary.”³⁹ CMS confirms that a hospital’s decision to withdraw its claim for Part A reimbursement and to seek Part B reimbursement instead does not negate the fact that the patient received medically necessary inpatient care, for purposes of Part A SNF coverage. CMS continues:

*In addition, the status of the beneficiaries themselves does not change from inpatient to outpatient under the Part B inpatient billing policy. Therefore, even if the admission itself is determined to be not medically necessary under this policy, the beneficiary would still be considered a hospital inpatient for the duration of the stay – which, if it occurs for the appropriate duration, would comprise a “qualifying” hospital stay for SNF benefit purposes so long as the care provided during the stay meets the broad definition of medical necessity described above.*⁴⁰

³⁶ *Id.*

³⁷ Medicare Benefit Policy Manual, Chapter 9, §40.1.5.

³⁸ Medicare Benefit Policy Manual, Chapter 8, §20.1.1.

³⁹ 78 Fed. Reg. 50495, 50921 (Aug. 19, 2013).

⁴⁰ *Id.*

A patient's receiving "medically necessary" care in the hospital, not the classification of the care as "inpatient," is the key factor for determining the patient's eligibility for Part A SNF coverage.

Conclusion Regarding CMS Authority to Define Inpatient Hospital Care

As the Court held in *Landers* and CMS itself recognized in 2005, CMS has authority under the Medicare statute to redefine inpatient status to count all time in the hospital. In Manual provisions, CMS recognizes that time in a hospital that is different from Medicare-covered hospital time can count for purposes of Part A SNF coverage. In the hospital rebilling option, CMS recognizes that receiving medically necessary care in the hospital is the key factor in determining Part A SNF coverage. CMS should confirm that time spent in observation or outpatient status qualifies a patient for Medicare Part A SNF coverage so long as the time in the hospital was medically necessary.

The Background statement available here⁴¹ shows CMS's ongoing consideration of this issue, CMS's repeated expressions of concern about the impact of extended observation stays on Medicare beneficiaries, and the findings of independent research on observation.

3. Ensure Access to Medicare-Covered Home Health Care

The Problem: COVID reminds us that most people want to remain home to receive needed care and that providing care at home is often safer for the patient and patient's community. Unfortunately, Medicare beneficiaries are increasingly unable to obtain Medicare-covered home health care for which they are eligible under the law. This is particularly true for people with on-going conditions and care needs, and for those who need home health aide services. Ensuring access to home health should be considered as an essential component of the new administration's work on Home and Community Based Services (HCBS).

Diminishing Access to Home Health Coverage

Medicare home health coverage can be an important source of financing for Medicare beneficiaries who need health care at home. To address the increasing need for home care and family support, and to consider possible solutions, one must first understand what Medicare coverage should be available under the law.⁴²

When properly implemented, the Medicare home health benefit provides coverage for a constellation of skilled and nonskilled services. Coverage is available for people with acute and chronic conditions, for skilled care to maintain or slow decline, and even if the services are

⁴¹ See Center for Medicare Advocacy websites at: <https://medicareadvocacy.org/cms-has-authority-under-existing-law-to-define-inpatient-care/>.

⁴² Note that much of this section on the home health benefit is adapted from the Center for Medicare Advocacy's Issue Brief: "Medicare & Family Caregivers" (June 2020), available at: <https://medicareadvocacy.org/wp-content/uploads/2020/06/Medicare-and-Family-Caregivers-June-2020.pdf>.

expected to extend over a long period of time.⁴³ However, even people with Medicare have difficulty obtaining and affording necessary home care. While there are legal standards that define who can obtain coverage, and for what services, the criteria are often narrowly construed and misrepresented, resulting in inappropriate barriers to Medicare and necessary care. This is increasingly true for home health aide services – the very kind of personal care services family caregivers are called on to provide, and the help both patients and caregivers need.

Under the law, Medicare authorizes up to 28 to 35 hours a week of home health aide (personal hands-on care) and nursing services combined.⁴⁴ While personal hands-on care does include bathing, it also includes dressing, grooming, feeding, toileting, and other key services to help an individual remain healthy and safe at home.⁴⁵ In the past, this level of home health aide coverage was actually available. The Center for Medicare Advocacy has helped many clients remain at home because these services were in place; currently such coverage and care is almost never obtainable. Data demonstrate this point. In 2019 the Medicare Payment Advisory Commission (MedPAC) reported that home health aide visits per 60-day episode of home care declined by 88% from 1998 to 2017, from an average of 13.4 visits per episode to 1.6 visits. As a percent of total visits from 1997 to 2017, home health aides declined from 48% of total services to 9%.⁴⁶

In short, the Medicare home health benefit is misunderstood, inaccurately articulated, and narrowly implemented. Medicare-certified home health agencies have all but stopped providing necessary, legally authorized home health aide services, even when patients are homebound and are receiving the requisite nursing or therapy to trigger coverage. CMS does not monitor or rebuke agencies for failure to provide this mandated and necessary care.

Recent Medicare Home Health Payment Changes

The problem of diminishing access to home health care has been exacerbated by recent changes in home health payment. On January 1, 2020, CMS implemented a new Medicare payment system for home health care called the “Patient Driven Groupings Model” (PDGM). PDGM changed home health agencies’ financial incentives and disincentives to admit or continue care for Medicare beneficiaries. Unfortunately, the financial motivations are often harmful to vulnerable beneficiaries, particularly those with chronic conditions and longer-term health care needs.

PDGM’s financial incentives include higher rates for the first 30 days of home care. Payments are also higher for beneficiaries who are admitted after an inpatient institutional stay (hospitals and skilled nursing facilities), and lower for those admitted from the community. (The “community” category includes hospital outpatients, including hospital patients in “Observation Status,” as well as patients who start care from home, without a prior hospital or SNF stay.) The

⁴³ 2 C.F.R. §408.48(a)-(b); MBP Manual, Ch. 7, §§401.1 and 70.1. See, *Jimmo v. Sebelius*, No. 11-cv-17 (D.Vt.), filed January 18, 2011; Settlement 2013; Corrective Action Plan 2017. See, <https://medicareadvocacy.org/medicare-info/improvement-standard/>. See, <https://www.cms.gov/Center/Special-Topic/Jimmo-Center>.

⁴⁴ 42 U.S.C. §1395x(m)(1)-(4). Note, receipt of skilled therapy can also trigger coverage for home health aides.

⁴⁵ 42 CFR §409.45(b)(1)(i)-(v). See also, Medicare Benefits Policy Manual, Chapter 7, §§50.1 and 50.2.

⁴⁶ Medicare Payment Advisory Commission (MedPAC), “Report to Congress: Medicare Payment Policy” (March 2019), Ch. 9, pp. 234-235, available at: http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch9_sec_rev.pdf?sfvrsn=0.

new payment model also reduced the billing period from 60 days to 30 days, and lowered the financial incentive to provide therapy by removing therapy service utilization payment thresholds.

The new Medicare payment system and shift in financial incentives have reduced access to necessary care. For instance, a *Home Health Care News* article states that “[s]tories of widespread layoffs of PTs, OTs and SLPs persist — and now new reports of agencies incorrectly telling their patients that Medicare no longer covers therapy under the home health benefit...”⁴⁷ Reductions in skilled therapy does not only harm the individual who needs that care, it can also end access to home health aides since aide services are dependent on the individual receiving skilled therapy or nursing. In response to misinformation and service changes in light of PDGM, CMS, to its credit, released a special edition *Medicare Learning Network (MLN) Matters* article on February 10, 2020.⁴⁸

Quality Reporting Measurements (QRM)

In addition, as the Center noted in our August 2020 comments to a recent proposed home health rule (CMS-1730-P),⁴⁹ CMS’ decision not to provide quality updates or proposals, such as ways to measure quality results for the care of people with longer-term or chronic conditions, in the proposed rule is disappointing because they are necessary. Table 28 (FR 39429) lists 5 of 14 OASIS-based HH QRM measures (36% of measures) that require a patient to improve in order for an agency to get “credit” for “quality service”.

CMS should not continue to ignore quality care for people for whom improvement is not a reasonable goal. CMS should propose measures to encourage agencies to help maintain the health of patients, or slow decline. Because CMS does not reward quality care to maintain patients’ conditions, home care agencies have yet another disincentive to admit such patients or to continue to their needed care.

Access to quality “maintenance care” is eroded and undermined by quality measures that do not include maintenance patients and clearly discriminate against them, through existing quality measures that reward care to patients who can improve. This conflicts with the *Jimmo* Settlement (discussed further below). This problem is further exacerbated when CMS penalizes agencies by 2% if agencies do not report their quality data (FR 39421). Quality matters for every patient, not just some. CMS should develop standards to measure quality care to maintain an individual’s condition or slow decline – not just to improve. Quality measurements should consider, and encourage the provision of necessary care to, all Medicare beneficiaries.

⁴⁷ *Home Health Care News*, “CMS Watching Home Health Providers Closely Amid Shifting Therapy Strategies” by Robert Holly, (Feb. 12, 2020), available at: <https://homehealthcarenews.com/2020/02/cms-watching-home-health-providers-closely-amid-shifting-therapy-strategies/>.

⁴⁸ CMS, MLN Matters article “The Role of Therapy under the Home Health Patient-Driven Groupings Model (PDGM)”, Number: SE20005 (Feb. 10, 2020), available at: <https://www.cms.gov/files/document/se20005.pdf>.

⁴⁹ Center comments to the proposed rule (Aug. 27, 2020) are available at: <https://medicareadvocacy.org/center-comments-on-proposed-home-health-rules/>.

Value Based Purchasing (VBP) was also not mentioned in the proposed rule. Although CMS considers VBP to be a separate consideration from quality measurements, agencies are further rewarded under VBP (in an annual increasing percentage through 2022), by criteria that mimics quality measurements, including improvement. VBP also rewards agencies that largely ignore maintenance patients, and penalizes agencies that help people maintain their conditions. CMS' QRM and VBP policies should be rectified immediately to properly include and measure quality care for patient who qualify and require home health services to maintain their conditions.

CMS Must Ensure the Full Scope of Medicare-Covered Services Are Actually Available for All Beneficiaries

There is a growing disconnect between what Medicare home care is coverable under the law, and what is actually available in practice. In particular, access to Medicare-covered home health aide services has greatly declined, even when individuals meet the law's qualifying criteria. This is due to a combination of factors, including changes in provider payment incentives and the perpetuation of myths such as the "improvement standard," despite court orders in the *Jimmo* litigation (discussed below).

In order to ensure that the law is followed, CMS should take several steps. As discussed above, in response to misinformation about and changes in the way providers are offering services in light of PDGM, CMS issued a special MLN article in February 2020. The MLN reminded providers that eligibility criteria for home health services "remain unchanged" and reiterated that there is no applicable improvement standard. Individuals who are homebound and receiving skilled care pursuant to a doctor's order should be able to receive the full array of care authorized by law so long as they meet the qualifying criteria. While welcome, the MLN has not reversed the growing trend limiting access to home care. Additional action is needed.

CMS should revamp all Medicare payment systems, modeling, and quality measures to create incentives for home health agencies to provide the full extent of necessary services available under the law. Further, it should oversee home health agencies to ensure they are adequately staffed and able to provide the complete array of Medicare-covered home health services. It should actively monitor and publicly report on the provision of home health aide services. CMS should also engage in an extensive education program targeting both providers (including home health agencies, prescribing physicians and other clinicians), and Medicare beneficiaries about the legal scope of the home health benefit, including the availability of skilled and non-skilled care for those who qualify. When necessary, CMS should require corrective action plans from providers that do not have sufficient staff and/or cannot provide or arrange to provide all Medicare covered services, including home health aides.⁵⁰

⁵⁰ See Center for Medicare Advocacy Issue Brief: "Medicare & Family Caregivers" (June 2020), available at: <https://medicareadvocacy.org/wp-content/uploads/2020/06/Medicare-and-Family-Caregivers-June-2020.pdf>.

4. Ensure Parity Between Traditional Medicare and Medicare Advantage and Promote Consumer Protections in Medicare Advantage

The Problem: The universal traditional Medicare program, preferred by most beneficiaries, has been neglected for years, while the private Medicare Advantage (MA) system has been repeatedly bolstered and promoted. This is leading to increased MA marketing and MA enrollment, even when it is not in the best interest of beneficiaries, Medicare, or taxpayers.

General Principle – Rebalance Growing Inequities Between Traditional Medicare and Medicare Advantage (MA)

Over the last several years, a number of legislative, regulatory, and policy changes have combined to create an imbalance between traditional Medicare and Medicare Advantage (MA).⁵¹ For example: coverage expansions such as the ability to provide new supplemental benefits were added for MA, but not for traditional Medicare; enrollment periods were changed to favor MA; and the scope of coverage by Medicare supplemental insurance policies (Medigaps) was restricted for some individuals. Further, despite provisions of the Affordable Care Act that reined in excessive overpayments to MA plans, there is still evidence that MA is costing the Medicare program more than traditional Medicare spends per individual, with mixed health outcomes.⁵²

In recent years, the imbalance has been exacerbated by a concerted effort on the part of the Trump Administration to steer beneficiaries toward enrollment in private MA plans through various means, including the program’s outreach and enrollment materials and marketing policies, rather than providing objective, neutral information about coverage options.⁵³

We urge CMS to make every effort to exercise its authority to reverse this trend. A new Administration, among other things, should rescind President Trump’s October 3, 2019 “Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors” (Executive Order 13890) which exacerbates an existing imbalance between traditional Medicare and Medicare Advantage, and demonstrated the Trump Administration’s ongoing efforts to maximize enrollment and the scope of coverage in MA plans. Section 3 of the EO directs the Secretary of HHS to, among other things, “ensure that, to the extent permitted by law, FFS [aka traditional, or Original] Medicare is not advantaged or promoted over MA with respect to its administration.” This Order should be retracted.

⁵¹ See, e.g., Center for Medicare Advocacy, Weekly Alert “Tipping the Scales Toward Medicare Advantage” (March 21, 2018), available at: <https://www.medicareadvocacy.org/tipping-the-scales-toward-medicare-advantage/>.

⁵² Center for Medicare Advocacy, Weekly Alert “Support Traditional Medicare by Leveling the Playing Field with Medicare Advantage” (August 15, 2019), available at: <https://www.medicareadvocacy.org/support-traditional-medicare-by-leveling-the-playing-field-with-medicare-advantage/>.

⁵³ Center for Medicare Advocacy, Weekly Alert “Improve and Expand Medicare: CMS Should Provide Objective Information About Medicare Options” (February 7, 2019), available at: <https://www.medicareadvocacy.org/improve-and-expand-medicare-cms-should-provide-objective-information-about-medicare-options/>.

Rein in MA Overpayments

While we recognize that CMS doesn't have complete authority over MA payment rates and formulas, we urge CMS to do what it can to rein in MA overpayments, including through more aggressive oversight of plan manipulation of risk-adjusted payments.

Various studies have attempted to document the scale of inappropriate MA coding intensity, or upcoding, and the resultant overcharges by MA plans. An investigation by the Center for Public Integrity, for example, found that Medicare paid MA plans nearly \$70 billion in "improper" payments, mostly from upcoding, from 2008 through 2013 alone.⁵⁴ More recently, a 2017 study published in *Health Affairs* found that coding intensity practices could result in overpayments to MA plans totaling \$200 billion over the next decade.⁵⁵

In April 2016, the General Accounting Office (GAO) issued a report entitled "Medicare Advantage: Fundamental Improvements Needed in CMS's Effort to Recover Substantial Amounts of Improper Payments."⁵⁶ The report states that CMS estimates that about 9.5% of its annual payments to Medicare Advantage (MA) organizations were improper – totaling \$14.1 billion in 2013 alone – "primarily stemming from unsupported diagnoses submitted by MA organizations." The report also highlighted the significant flaws in CMS' current efforts to address and recoup such payments, including execution of the Risk Adjustment Data Validation (RADV) audit process.

A December 2019 Office of Inspector General (OIG) report⁵⁷ concluded that "[b]illions of estimated risk-adjusted payments supported solely through chart reviews raise potential concerns about the completeness of payment data submitted to CMS, the validity of diagnoses on chart reviews, and the quality of care provided to beneficiaries." Risk-adjusted payments, the report noted, "may create financial incentives for [MA plans] to make beneficiaries appear as sick as possible to obtain higher payments. CMS estimates that from 2013 through 2016, Medicare paid \$40 billion in overpayments that resulted from plan-submitted diagnoses that were not supported by beneficiaries' medical records."

The Center for Medicare Advocacy is deeply concerned by these ongoing improper payments to MA plans and CMS' lack of progress in recouping previous payments and deterring future misconduct. In order to ensure that the traditional Medicare program is not further

⁵⁴ See, e.g., Center for Public Integrity, "Why Medicare Advantage costs taxpayers billions more than it should" (June 2014), available at: <https://www.publicintegrity.org/2014/06/04/14840/why-medicare-advantage-costs-taxpayers-billions-more-it-should>. See, also, Center for Public Integrity, "Medicare Advantage audits reveal pervasive overcharges" (August 2016), available at: https://www.publicintegrity.org/2016/08/29/20148/medicare-advantage-audits-reveal-pervasive-overcharges?utm_source=email&utm_campaign=watchdog&utm_medium=publici-email&goal=0_ffd1d0160d-631decf34e-100055089&mc_cid=631decf34e&mc_cid=52f7afd44e.

⁵⁵ Kronick, R., "Projected Coding Intensity In Medicare Advantage Could Increase Medicare Spending By \$200 Billion Over Ten Years," (Health Affairs: February 2017), available at: <http://content.healthaffairs.org/content/36/2/320.abstract>.

⁵⁶ GAO, "Medicare Advantage: Fundamental Improvements Needed in CMS's Effort to Recover Substantial Amounts of Improper Payments" (April 2016), available at: www.gao.gov/assets/680/676441.pdf.

⁵⁷ Department of Health and Human Services, Office of Inspector General (OIG) report "Billions in Estimated Medicare Advantage Payments From Chart Reviews Raise Concerns" (December 2019), available at: <https://oig.hhs.gov/oei/reports/oei-03-17-00470.pdf>.

disadvantaged by inappropriate overpayments to MA plans, CMS must employ more rigorous oversight of MA payment.

Among the steps CMS can take: First, lift the current suspension on Risk-Adjustment Data Validation program (RADV) audits during the current Public Health Emergency (PHE) – given the level of profits the insurance industry has made during the pandemic, coupled with the fact that CMS has clarified that MA plans can shift the cost of vaccines on to traditional Medicare, resumption of such audits are warranted. Second, ramp up RADV audits in order to recoup wasteful payments to MA plans. Third, increase the annual coding intensity adjustment above the statutory minimum of 5.90%.

Fourth, enhance oversight of MA plan sponsors’ in-home risk assessments to ensure that the services provided to beneficiaries through these visits are meaningful and effective, not simply a means for collecting risk adjustment diagnoses without ensuring that meaningful follow-up care is delivered. We urge CMS to adopt the initial proposal in its draft 2015 Call Letter to exclude, for payment purposes, diagnoses from in-home risk assessments that were not confirmed by a subsequent clinical encounter (a policy change also supported by MedPAC). We are concerned that voluntary best practices – a proposal from the 2016 Call Letter – will not achieve CMS’ goal of linking heightened risk scores to care that addresses beneficiaries’ health needs. Use of such best practices should only be an interim step while CMS works to develop a strong evidence-based in-home assessment tool. We again urge CMS to exclude, for payment purposes, diagnoses identified during a home visit that are not confirmed by a subsequent clinical encounter. Simply enhancing a risk profile without benefiting enrollees serves no useful purpose to the Medicare program or its beneficiaries.

Oversight and Enforcement

We urge CMS to increase its oversight and management of the MA and Part D markets through multiple means, including the Star Ratings program, and audit and enforcement procedures. These tools play a critical role in ensuring not only that MA and Part D plans are optimally serving their enrollees but also that taxpayer dollars are well spent.

We share the concerns voiced by Senator Sherrod Brown and colleagues regarding the sufficient oversight of the MA program, including addressing MA overpayments, discussed above.⁵⁸ Towards **this end, we encourage CMS to consider the following:**

Enhance Oversight of MA Coverage and Care Denials

For decades the Center for Medicare Advocacy has helped Medicare beneficiaries with significant MA problems and coverage denials. We have witnessed and challenged inappropriate denials of coverage and care by myriad Medicare Advantage plans. In September 2018, the

⁵⁸ Letter to CMS Administrator Verma from Senators Brown, Murphy, Sanders, Blumenthal, Klobuchar and Stabenow (September 13, 2019), available at: <https://www.brown.senate.gov/imo/media/doc/CMS%20MA%20Oversight%20Letter%20%2009.13.19.pdf>.

Office of Inspector General (OIG) issued a report entitled “Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials.”⁵⁹ Among findings such as MA plans overturn 75 percent of preauthorization and payment denials, but beneficiaries and providers appeal only 1 percent of denials to the first level of appeal, OIG stated:

“[a] central concern about the capitated payment model used in Medicare Advantage is the potential incentive for [Medicare Advantage Organizations, or MAOs] to inappropriately deny access to services and payment in an attempt to increase their profits. An MAO that inappropriately denies authorization of services for beneficiaries, or payments to health care providers, may contribute to physical or financial harm and also misuses Medicare Program dollars that CMS [Centers for Medicare & Medicaid Services] paid for beneficiary healthcare. Because Medicare Advantage covers so many beneficiaries (more than 20 million in 2018), even low rates of inappropriately denied services or payment can create significant problems for many Medicare beneficiaries and their providers.”

In response to these concerns, OIG recommended that CMS: (1) enhance its oversight of MAO contracts including those with extremely high overturn rates and/or low appeal rates and take corrective action as appropriate; (2) address persistent problems related to inappropriate denials and insufficient denial letters in Medicare Advantage; and (3) provide beneficiaries with clear, easily accessible information about serious violations by MAOs. Among these recommendations, OIG stated that CMS should take program-level action to address persistent problems such as: (1) insufficient denial letters issued to beneficiaries and providers, (2) insufficient outreach before issuing denials, and (3) incorrect clinical decisions.

Although OIG noted that CMS concurred with all of OIG’s recommendations, it stated that CMS did not fully explain how it plans to implement the recommendations, including “how it planned to enhance oversight of MAOs with extremely high overturn rates or extremely low appeal rates” and what actions “it plans at the program-level to address these persistent problems.”

It is beyond time for CMS to act upon these recommendations and hold MA plans accountable that routinely issue inappropriate denials for necessary care that is covered under the law.

Review Prior Authorization and Decision-Making Tools

On December 10, 2020, CMS announced a proposed rule addressing health plans’ use of prior authorization, but specifically (yet inexplicably) excluded Medicare Advantage plans. We strongly urge CMS to include MA plans in any effort to ensure that the use of prior authorization is more equitable for plan enrollees.

At the time of transition between administrations, Congress is debating a bill that would take some important first steps to address MA plan’s overuse of Prior Authorization (PA) - HR 3107,

⁵⁹ Department of Health and Human Services (DHHS) Office of Inspector General (OIG) report “Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials” (September 2018) (OEI-09-16-00410), available at: <https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf>.

the “Improving Seniors’ Timely Access to Care Act of 2019.” The current draft of this bill should go further in protecting beneficiaries from misuse of PA by plans. This would include requiring plans to disclose when they rely on clinical decision-making tools, including software that is considered “proprietary.” Software/clinical decision-making tools (such as NaviHealth, InterQual, Milliman) are increasingly used by plans and providers to make coverage decisions without an opportunity for individuals – to whom such criteria is applied - to analyze such criteria.

In the Center for Medicare Advocacy’s experience, when we are able to actually see recommendations made by such software, the coverage criteria is often more restrictive than Medicare law and guidance. The increased use of such tools hurts beneficiaries and providers, and absent restricting their use, we need to learn more about them. Further, contrary to law that requires an individual assessment of each beneficiary’s qualification for coverage, these tools lead to blanket “rules of thumb” that determine beneficiaries’ access to coverage and care, often in conflict with clinical judgment. CMS should study, or encourage study by other entities such as GAO or OIG, to ensure such decision-making tools do not conflict with Medicare law and are available for review by the public.

Enhance Audit Capacity and Increase Transparency on Enforcement Actions

We urge CMS to revisit the agency’s prior proposal to increase audit and inspection authority. In a 2015 proposed rule, CMS details the criteria by which it determines which MA and Part D plan sponsors are audited each year and acknowledges that limited resources allow the agency to perform annual audits on only 10% of plan sponsors—30 of 300. CMS previously proposed, but chose not to finalize, a rule requiring plan sponsors to hire independent auditors. Given persistently poor plan audit results, namely involving appeals and grievances, we ask CMS to revisit this proposal.⁶⁰

Align Star Ratings and Enforcement Actions

The Medicare program now relies on consumers making decisions about their own coverage options based on a multitude of private plan offerings through Medicare Advantage and Part D,. Among the tools consumers have to compare prospective plans are published plan star ratings. As noted by 2018 Office of Inspector General (OIG) report analyzing MA plan denials, though, “because audit violations will no longer be reflected in Star Ratings, beneficiaries may be unaware of MAO performance problems when selecting a plan.”⁶¹

Any disconnect between audit scores and the star ratings system can be a source of confusion for people seeking to evaluate and compare plan quality. We continue to strongly urge CMS to ensure that the star rating system does not camouflage or minimize plan behaviors that put Medicare enrollees at risk. When CMS determines that a plan’s conduct poses a serious threat to the health and safety of beneficiaries, CMS should accurately signal this assessment through star ratings, providing beneficiaries with a clear tool that helps them fully evaluate and compare

⁶⁰ 80 Fed Reg 7919 (February 12, 2015).

⁶¹ Department of Health and Human Services (DHHS) Office of Inspector General (OIG) report “Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials” (September 2018) (OEI-09-16-00410), available at: <https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf>.

health plans. Of particular concern is the repeated finding of the same serious deficiencies in audit scores while star ratings continue to rise. To address this imbalance, it is critically important that star ratings incorporate audit measures and reflect audit results in meaningful ways, while CMS continues to impose significant sanctions and penalties when serious deficiencies are identified.⁶²

As recommended by OIG in their 2018 report, “CMS could also revisit policy options for adjusting Star Ratings in response to audits and enforcement actions, such as adding a new Star Ratings measure that takes enforcement actions into account, or by directly adjusting an MAO’s overall and summary Star Ratings in response to enforcement actions. This would help to ensure that Star Ratings serve as a “one-stop shop” for beneficiaries to evaluate differences in performance among MAOs.”

Moreover, more recently, according to the independent Medicare Payment Advisory Commission (MedPAC), there are concerns about the quality of the ratings themselves. In a summary of a March 2020 report to Congress,⁶³ MedPAC states that it “continues to have concerns with the MA star rating system, which serves as the basis for plan quality bonuses and public reporting of plan quality. MA star ratings continue to be determined at the contract level. Because contracts can cover wide (and discontinuous) geographic areas and quality results are often determined based on only a small sample of beneficiary medical records, Medicare and beneficiaries lack important information about the quality of care of MA plans in their market. As a result, the Commission can no longer provide an accurate description of the quality of care in MA.” We urge CMS to address the problems raised by MedPAC.

Enforce Anti-Discriminatory Benefit Design Protections for ESRD Enrollees

Pursuant to the CURES Act, individuals with End Stage Renal Disease (ESRD) will be permitted to join MA plans starting in 2021. CMS must act to ensure that MA plan benefit packages do not discriminate against individuals with ESRD. On the one hand, §3202 of the Affordable Care Act (ACA) states that cost-sharing under MA plans cannot exceed the cost-sharing imposed under traditional Medicare for three specific services—chemotherapy administration, renal dialysis services, and skilled nursing care. Under Part B of Medicare, the coinsurance rate for dialysis is 20%. On the other hand, federal law contains strong anti-discrimination provisions, including a requirement that “[t]he Secretary shall not approve a plan of an organization if the Secretary determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals with the organization.” 42 U.S. Code § 1395w–22(b)(1). Further, federal regulations require CMS, in its review of approval of MA benefits and associated cost-sharing, to ensure that “MA organizations are not designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services.” 42 CFR §422.100(f)(2).

⁶² For more feedback on star ratings and enforcement actions, see the Center’s comments to the Draft 2018 Call Letter at: <https://www.medicareadvocacy.org/center-comments-on-draft-2018-medicare-advantage-call-letter/>.

⁶³ MedPAC (March 2020) available at: http://www.medpac.gov/docs/default-source/fact-sheets/march_2020_medpac_fact_sheet_sec.pdf?sfvrsn=0.

Late in 2019, the Center for Medicare Advocacy was alerted that a Kaiser Permanente Medicare Advantage plan in Southern California notified enrollees it was increasing the coinsurance it charged for dialysis from \$0 in 2019 to 20% coinsurance in 2020. By virtue of the current system of MA regulatory oversight, this was a benefit package change that was analyzed and approved by CMS for the 2020 plan year. An assessment of 2021 MA plan offerings, unfortunately, shows that 20% coinsurance charges will be the norm.

Imposition of cost-sharing is generally intended, in part, to prevent consumers from over-utilizing health care services. While this is not a universally accepted notion, dialysis is certainly not a service that is over-utilized by an individual with ESRD. Instead, it is a regular, medically necessary service that is required by this population.

Charging maximum cost-sharing permissible under the law for a particular service used by a particular population could be viewed as discriminatory on its face. If such benefit design becomes the norm in 2021 rather than an outlier, it will likely be a race to the bottom among MA plans to try to dissuade enrollment by individuals with ESRD, despite new requirements that they must now accept all comers. Even with the mandatory MA out-of-pocket caps, charging such a high rate for dialysis will be cost-prohibitive for many individuals with ESRD. This will be harmful to their health should they be unable to afford such ongoing costs prior to the triggering of a MOOP. We urge CMS to take action to prevent discriminatory benefit design in MA plans relating to people with ESRD by prohibiting – or at least minimizing – cost-sharing for dialysis. CMS should issue clear statements to MA plans that benefit designs that charge 20% coinsurance for dialysis will be deemed discriminatory and will not be tolerated.⁶⁴

Rescind or Revise New Flexibilities re: MA Uniformity Standards and Meaningful Differences

In recent years, Congressional and CMS actions to ease requirements for MA plans concerning the provision of benefits has made things more complex for beneficiaries. In particular, changes such as loosening uniformity standards, which required plan sponsors to offer the same benefits at the same cost-sharing for all enrollees in a plan’s service area, has made beneficiary decision-making about coverage options extraordinarily difficult. Beneficiary “choice” and plan “flexibility” should not be stand-ins for adequate consumer protections. The processes for offering and selecting private Medicare plans should not be designed for the savviest consumer, as is now the case; rather, there must be standard, baseline means of plan comparison.

There is a large body of research and analysis that explores the challenges consumers currently face in making choices about their health insurance coverage, including when there are a multitude of plan options, with little to no standardization.⁶⁵ Much of the findings in this work

⁶⁴ For further discussion, see Center for Medicare Advocacy Comments to CMS’ Proposed 2021 C & D Rule (April 6, 2020), available at: <https://medicareadvocacy.org/wp-content/uploads/2020/04/CMA-CD-Comments-2020.pdf>.

⁶⁵ Here is a sample of such research and analysis: “Realizing Health Reform’s Potential : What States Are Doing to Simplify Health Plan Choice in the Insurance Marketplaces”; Christine H. Monahan, Sarah J. Dash, Kevin W. Lucia, and Sabrina Corlette; *The Commonwealth Fund*, December 2013 (available at: http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2013/Dec/1720_Monahan_what_states_are_doing_simplify_rb.pdf); “The Evidence is Clear: Too Many Health Insurance Choices Can Impair, Not Help

weigh against the recent actions by Congress and CMS, including those that have greatly loosened both uniformity and meaningful differences standards.⁶⁶

We urge CMS to reinstate stronger uniformity requirements. Should CMS choose to maintain the current, weakened standards, however, it must, at a minimum, include basic consumer protections and oversight included in the Value Based Insurance Design (VBID) demonstration, as outlined in previous comments the Center for Medicare Advocacy has submitted to CMS.⁶⁷

Rather than giving MA plan sponsors the flexibility to vary their benefits significantly even within a given plan, we urge CMS to pursue the opposite strategy. In the interest of beneficiaries, CMS should work towards standardizing MA plan benefit packages. Many people continue to struggle to select among several MA plans and multiple, complex plan variables, most simply do not switch from year to year.⁶⁸

To encourage efficient plan selection, distinctions among plans must be made more meaningful. CMS should standardize MA benefit packages, as is done for supplemental Medicare/“Medigap” plans (i.e., Plan A, Plan B, Plan C), to encourage “apples-to-apples” comparisons among plan options. Confusion surrounding Medigap policies – both concerning benefits offered and value for premiums paid – significantly diminished when Medigap plans were standardized in the 1990s. Medicare beneficiaries shopping for and comparing MA plans would similarly benefit

Consumer Decision Making”, Lynn Quincy and Julie Silas; *Consumers Union*, November 2012 (available at: http://consumersunion.org/wp-content/uploads/2012/11/Too_Much_Choice_Nov_2012.pdf); “What’s Behind the Door: Consumers’ Difficulties Selecting Health Plans” Lynn Quincy; *Consumers Union*, January 2012 (available at: http://consumersunion.org/wp-content/uploads/2013/03/Consumer_Difficulties_Selecting_Health_Plans_Jan2012.pdf); “Cognitive Functioning and Choice between Traditional Medicare and Medicare Advantage”; J. Michael McWilliams, Christopher C. Afendulis, Thomas G. McGuire, and Bruce E. Landon; *Cognitive Functioning and Choice between Traditional Medicare and Medicare Advantage* Health Affairs, September 2011 (available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3513347/>); “Medicare Part D: Simplifying the Program and Improving the Value of Information for Beneficiaries”, Jack Hoadley; *The Commonwealth Fund*, May 2008 (available at: <http://www.commonwealthfund.org/Publications/Issue-Briefs/2008/May/Medicare-Part-D-Simplifying-the-Program-and-Improving-the-Value-of-Information-for-Beneficiaries.aspx>); “Medicare Advantage: Options for Standardizing Benefits and Info to Improve Consumer Choice”, Ellen O’Brien and Jack Hoadley; *The Commonwealth Fund*, April 2008 (available at: (http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2008/Apr/Medicare%20Advantage%20Options%20for%20Standardizing%20Benefits%20and%20Information%20to%20Improve%20Consumer%20Choice/OBrien_Medicare_Advantage_options_1117_ib%20pdf.pdf)); and “Informed Choice: The Case for Standardizing and Simplifying Medicare Private Health Plans,” Precht, P., Lipschutz, D. and Burns, B. (California Health Advocates and Medicare Rights Center: September 2007), available at: <http://cahealthadvocates.org/pdf/advocacy/2007/InformedChoice.pdf>.

⁶⁶ See the Center for Medicare Advocacy’s “Special Report: Recent Changes in Law, Regulations and Guidance Relating to Medicare Advantage and the Prescription Drug Benefit Program” (September 2018) available on our website here: <https://www.medicareadvocacy.org/wp-content/uploads/2018/09/Report.-Summary-2019-Call-letter-and-C-D-Rule-1.pdf>; also see Center Comments on Proposed Rule for Medicare Parts C & D (January 2018) available at: <https://medicareadvocacy.org/center-comments-on-proposed-rule-for-medicare-parts-c-d/>.

⁶⁷ See, e.g., the Center for Medicare Advocacy’s January 2018 comments to a proposed C & D rule at: <https://medicareadvocacy.org/center-comments-on-proposed-rule-for-medicare-parts-c-d/>

⁶⁸ See, e.g., reports by the Kaiser Family Foundation <https://www.kff.org/medicare/issue-brief/no-itch-to-switch-few-medicare-beneficiaries-switch-plans-during-the-open-enrollment-period/> and <https://www.kff.org/medicare/issue-brief/more-than-half-of-all-people-on-medicare-do-not-compare-their-coverage-options-annually/>.

from being able to compare standardized MA benefit packages between and among plan sponsors.

If CMS does not move to standardization, and retains these new MA benefit flexibilities, CMS must at least strengthen requirements surrounding the marketing of Special Supplemental Benefits for the Chronically Ill (SSBCI), as described further below.

MA Network Adequacy

Provisions of CMS' final 2021 Part C & D rule weakened MA network adequacy requirements. 85 Fed Reg 33796 (June 2, 2020). These provisions should be rescinded, specifically: the reduction in the percentage of beneficiaries that must reside within the maximum time and distance standards in non-urban counties from 90 percent to 85 percent in order for an MA plan to comply with network adequacy standards; the 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards when they contract with telehealth providers; and the elimination of time and distance limits from network adequacy requirements for dialysis facilities.⁶⁹

Further, in 2015 the General Accounting Office (GAO) released a report entitled "Medicare Advantage: Actions Needed to Enhance CMS Oversight of Provider Network Adequacy". GAO examined several factors relating to CMS' oversight of MA organization (MAO) network adequacy, and made corresponding findings, including: how CMS defines network adequacy and how its criteria compares with other programs; how and when CMS applies its network adequacy criteria; the extent to which CMS conducts ongoing monitoring of MA organization networks; and how CMS ensures that MA organizations inform beneficiaries about terminations.

While CMS has made efforts to address some of the deficiencies highlighted by GAO, so far such efforts appear to be primarily directed at provider directories alone, and, as discussed below, much more is needed. CMS noted in the draft 2016 Call Letter that "[t]he data collected through our monitoring activities could drive additional reviews of network adequacy, as well as future monitoring and/or audit-based activities" [emphasis added]. We urge CMS to more broadly expand its oversight and definition of network adequacy, as suggested by GAO.

Among the ways CMS could update MA network adequacy standards is to include essential community providers among the types of providers, similar to the requirements for qualified health plans under the Affordable Care Act (ACA) – see, e.g., 45 CFR §156.230(a)(2) "network that is sufficient in number and types of providers, including providers that specialize in mental health and substance abuse services, to assure that all services will be accessible without unreasonable delay" and 45 CFR §156.235 – "reasonable and timely access to a broad range of [...] providers for low-income, medically underserved individuals".

⁶⁹ See discussion in the Center's Weekly Alert "Final Rule for Medicare Parts C and D Includes Weakened Standards for Medicare Advantage Networks" (May 28, 2020), available at: <https://medicareadvocacy.org/final-rule-for-medicare-parts-c-and-d-includes-weakened-standards-for-medicare-advantage-networks/>.

MA Provider Directories

CMS has recognized a long-standing problem concerning the accuracy of MA plan provider directories. For example, in 2017, CMS announced the agency’s findings from a review of 54 MA organizations, which showed widespread inaccuracies in MA provider directories.⁷⁰ In response, the agency released additional guidance reiterating the rules MA organizations must follow for provider directories and took appropriate compliance actions. The draft 2020 Call Letter noted that “there has been a lack of improvement in the accuracy of provider directories over the past three years.” Directory inaccuracies can present significant challenges for enrollees—up to and including a potential lack of access to care and significant out-of-pocket costs. We urge CMS to focus its attention on the undue burden that inaccurate, hard-to-access, and non-searchable provider directories place on beneficiaries. This is even more critical as CMS plans to make provider directories available through the Medicare Plan Finder in the coming years.

Provider Network Terminations

CMS should strengthen consumer protections surrounding MA plan mid-year provider network terminations. The most effective way to protect consumers from being trapped in their plans after their own doctors are involuntarily terminated is to prohibit MA plans from terminating network providers mid-year without cause. Not only did CMS retreat from this option in the final 2015 Call Letter, but there has been no attempt to extend the current 30-day advance notice to affected beneficiaries, as also suggested in the 2015’s Draft Call Letter. Further, CMS has failed to strengthen or otherwise expand the right to a limited special enrollment period (SEP), which is only available to beneficiaries affected by “significant” network terminations. In addition, the availability of this limited SEP right is not adequately expressed in beneficiary-oriented materials, including those issued by plan sponsors (e.g. the Annual Notice of Change) or by CMS (e.g. Medicare & You and the www.medicare.gov website). More accurate provider directories, while a welcome improvement in consumer information, is not a solution to this problem.

Rescind Policy Allowing MA Plans to Apply Step-Therapy to Part B Drugs

This provision has weakened beneficiary protections, specifically access to Part B drugs without being subject to step therapy (aka “fail first”), in misguided reliance on a flawed appeals system. This impacts some of the sickest Medicare beneficiaries, who may not have the wherewithal to engage in a difficult appeals process, even if they aware of their right to do so.⁷¹

⁷⁰ CMS, “Online Provider Directory Review Report” (January 2017), https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Final_01-13-17.pdf.

⁷¹ See discussion in the Center’s comments on “Modernizing Part D and Medicare Advantage” (January 2019), available at: <https://medicareadvocacy.org/center-comments-on-modernizing-part-d-and-medicare-advantage/>.

*Reinstate Plan Reporting Requirements re: Appeals*⁷²

Access to information regarding a plan sponsor's number and outcome of expedited appeals is critical information to have before enrolling in a Medicare Advantage plan. One could use this information to evaluate and compare Medicare Advantage plan performance and specifically how they treat their members who are receiving covered care in various settings. In fact when we speak to a Medicare beneficiary who is considering enrolling in an MA plan we often advise them to request information regarding appeals to fully evaluate the plan. If, for example, a Medicare Advantage plan reports a high number of expedited appeals and denials per case one might seriously consider not enrolling in that Medicare Advantage plan.

Currently, Medicare Advantage plans are required to disclose grievances and appeals information regarding the number of disputes and their disposition to any MA plan eligible individual who requests this information.⁷³ The language in both the Social Security Act and the Medicare regulations is clear and unambiguous. MA plans must report all appeals. Both the Social Security Act and the Medicare regulations specifically require that upon request of a MA eligible individual, a MA plan must provide to the individual information on the number of grievances, redeterminations, and appeals and on the disposition in the aggregate of such matters.⁷⁴ The regulations specifically refer to "Appeals according to §422.578 et. seq."⁷⁵ This includes expedited and second level appeals.

On September 24, 2020 the Director of the Medicare Enrollment & Appeals Group from the Centers for Medicare and Medicaid Services (CMS) issued a memorandum to plan sponsors regarding "[Revised Appeal and Grievance Data Form, Form CMS-R-0282](#)" that outlined changes to the Appeal and Grievance Data Form. The changes were made "[i]n an effort to identify opportunities to reduce MA plan burden and provide a simplified, easy to read report to MA plan eligible individuals..." (emphasis added). The revised data form specifically removed the following data elements:

- Expedited appeals
- Disposition of expedited appeals
- IRE (level 2) appeals
- Disposition of IRE (level 2) appeals
- Withdrawals

In an era of regulatory rollback and general deference to private plans, and likely some pressure from the MA industry, in essence, CMS decided that it is o.k. for MA plans to not fully comply with the clear reading of the Social Security Act and the Medicare regulations by not having to

⁷² See Center for Medicare Advocacy Weekly Alert "[MA Plans Allowed to Report Less Data about Appeals Outcomes](#)" (October 1, 2020), available at: <https://medicareadvocacy.org/ma-plans-allowed-to-report-less-data-about-appeals-outcomes/>

⁷³ §1852(c)(2)(C) of the Social Security Act and 42 C.F.R. §422.111(c)(3).

⁷⁴ §1852(c)(2)(C) of the Social Security Act and 42 C.F.R. §422.111(c)(3).

⁷⁵ See 42 C.F.R. Subpart M – Grievances, Organization Determinations and Appeals.

report information about expedited or second level appeals. CMS expressly states in the revised Form Instructions CMS-R-0282 that the MA plan will meet the disclosure requirements set forth in the regulations using the revised form.⁷⁶ However, clearly missing from the revised form is data regarding expedited and second level appeals, which is included in the disclosure requirements of the MA regulations. This is important information for beneficiaries and oversight of MA plans.

CMS touts these changes as reducing “MA plan burden” and creating an “easy to read report” for MA eligible individuals as though it’s a win-win situation for everyone. Actually, the Medicare beneficiary comes out on the losing end because they have been stripped of a very important protection – the ability to fully evaluate an MA plan before enrollment. In general, it is becoming more difficult to obtain accurate information about MA plans. For example, CMS continues to paint MA plans in the most favorable light, including downplaying any drawbacks, as discussed in a recent Center for Medicare Advocacy *CMA Alert* concerning the 2021 *Medicare & You* handbook, discussed further below. In addition, as noted above, the Medicare Payment Advisory Commission (MedPAC) has called into question the accuracy of plan quality ratings, one of the primary tools that consumers have to compare plans.

More specifically, information about how a given plan handles appeals is critically important to determine access to care. As noted by Kaiser Family Foundation,⁷⁷ virtually all MA plans use prior authorization for items and services, which often serves as a barrier to accessing care and is often the trigger for filing an appeal. As noted above, a 2018 Dept. of Health and Human Services Office of Inspector General (OIG) report⁷⁸ found “widespread and persistent problems related to denials of care and payment in Medicare Advantage’ plans”. The report’s findings included: when beneficiaries and providers appealed preauthorization and payment denials, MA plans “overturned 75 percent of their own denials”; however, OIG found that “beneficiaries and providers appealed only 1 percent of denials to the first level of appeal.” In short, the public needs more – not less – information about MA appeals.

CMS does not have the authority to allow plans and providers to only partially comply with the Social Security Act and regulations. CMS should immediately rescind this memorandum, uphold the Social Security Act and Medicare regulations, and require that all MA plans fully comply with the law. As more people enroll in MA plans CMS should be more concerned with beneficiary protections and less concerned with burdens to the major insurance companies that provide MA plans.

Expand Services for Which Cost-Sharing May Not Exceed Traditional Medicare’s Cost Sharing

Section 3202 of the Affordable Care Act (ACA) states that cost-sharing under MA plans cannot exceed the cost-sharing imposed under traditional Medicare for three specific services—

⁷⁶ CMS <https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/downloads/AppGrievDataFormINS.pdf>.

⁷⁷ Kaiser Family Foundation report (April 2020), available at: <https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage-in-2020/>.

⁷⁸ HHS OIG report “Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials” (Oct. 2018), available at: <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>.

chemotherapy administration, renal dialysis services, and skilled nursing care. Title 42 of the Code of Federal Regulations, §422.100(j) states that “On an annual basis, CMS will evaluate whether there are service categories for which MA plans' in-network cost sharing may not exceed that required under Original Medicare and specify in regulation which services are subject to that cost sharing limit.”

Since the implementation of the ACA, CMS has not expanded this important consumer protection beyond these three enumerated services. We urge CMS to expand this protection to include durable medical equipment (DME – currently subject to 20% coinsurance under Part B), home health services (currently no cost-sharing for individuals in traditional Medicare).

[Note that the next sections address Part C & D Enrollment/Disenrollment Issues and Beneficiary Education & Information, respectively. While both areas include inequities between Medicare Advantage and traditional Medicare, there are recommendations in these sections that are unrelated to the inequities, but nonetheless would improve the Medicare program for beneficiaries.]

a. Parts C and D Enrollment/Disenrollment Issues

Need for Additional Special Enrollment Periods (SEPs)

In CMS’ proposed 2021 C & D rule, it sought comment on whether there are other exceptional circumstances it has not identified for which it should consider establishing an SEP. In the Center’s comments⁷⁹, first, we urged CMS to articulate in regulatory language (either in the SEP for individuals affected by a federal employee error or a separate entry) that an SEP for exceptional circumstances may exist for individuals who rely, to their detriment, on errors in the Medicare Plan Finder (MPF) or other CMS-issued or managed information platforms.

Second, while there is an existing SEP for significant change in an MA provider network, it is only triggered when a threshold of terminations is met. As CMS notes in the preamble to the proposed 2021 C & D rule, “CMS considers significant changes to provider networks to be those that go beyond individual or limited provider terminations that occur during the routine course of plan operations and affect, or have the potential to affect, a large number of the MAO’s enrollees.” P. 9119. We urge CMS to revise this SEP so that it can be used when an individual plan enrollee’s provider is terminated without cause. While more limited provider terminations may “occur during the routine course of plan operations”, it does not matter to an individual if there are a specific number of other enrollees affected by a threshold number of provider terminations. That individual may have joined that plan specifically because their provider contracts with it, and have developed a relationship with that provider they wish to maintain.

Third, CMS has revised SEP rights available to individuals dually eligible for Medicare and Medicaid, Medicare Savings Programs (MSPs), and the Part D low income subsidy (LIS). Such

⁷⁹ For further discussion of SEPs, see the Center for Medicare Advocacy’s Comments to CMS’ Proposed 2021 C & D Rule (April 6, 2020), available at: <https://medicareadvocacy.org/wp-content/uploads/2020/04/CMA-CD-Comments-2020.pdf>.

right is now only available once per calendar quarter for the first nine months of the calendar year. For the reasons articulated in our comments to the 2018 proposed rule implementing these changes⁸⁰, we urge CMS to reverse this change and reinstate open enrollment for these individuals.

Finally, we urge CMS to establish an SEP right for individuals in MA and Part D plans who are impacted by significant changes in their plan benefits from one year to the next, e.g. significantly higher premiums or reduced benefits. This is particularly important for individuals with stand-alone PDPs since they do not have the same option to change plans during the first three months of the year afforded to those who begin the year enrolled in an MA plan (pursuant to the MA-OEP).

Changes experienced by enrollees of Humana Part D plans between 2019 and 2020 are illustrative. In a “first look” at 2020 Part D plan offerings, the Kaiser Family Foundation⁸¹ highlighted changes to offerings made by Humana in the context of Part D enrollees who would be paying more or less in premiums if they did not change plans:

Two-thirds of Part D enrollees without low-income subsidies (9.0 million enrollees) will see their monthly premium increase in 2020 if they stay in their same plan, while one-third (4.3 million) face premium decreases. As an example, the 1.9 million enrollees without low-income subsidies in the Humana Walmart Rx Plan, the third most popular PDP in 2019, will see their monthly premium double in 2020, from \$28 to \$57, unless they switch plans. This is due to plan changes and consolidations, with Humana consolidating two of its PDPs (Humana Walmart Rx and Humana Enhanced) into one PDP for 2020 and renaming it Humana Premier Rx, with a \$57 monthly premium.

We note that most people who are enrolled in a given plan tend to rely on that plan remaining more or less the same, and, as a consequence, many people do not carefully scrutinize their ANOC or other plan documents describing annual changes. Such individuals should not be penalized if their plan benefits change significantly from one year to another. If a plan substantially changes its benefits to an enrollee’s detriment, at the very least such an individual should get the same SEP right as is provided for plan non-renewals or terminations.

b. Beneficiary Information and Education

General Statement re: Eliminating Bias Towards Medicare Advantage Plans

Since Fall of 2017, the Center for Medicare Advocacy and other consumer advocacy organizations have highlighted that under the Trump Administration, in a marked change to previous practice, CMS’ outreach and enrollment materials have encouraged beneficiaries to choose a private Medicare plan over traditional Medicare, instead of objectively presenting

⁸⁰ Center for Medicare Advocacy comments to 2018 Proposed C&D rule (January 2018) available at: <https://www.medicareadvocacy.org/center-comments-on-proposed-rule-for-medicare-parts-c-d/>.

⁸¹ Kaiser Family Foundation “Medicare Part D: A First Look at Prescription Drug Plans in 2020” (Nov. 2019), available at: <https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2020/>.

enrollment options.⁸² Rather than presenting differences between traditional Medicare and MA in a neutral, unbiased manner, CMS has been overplaying the pluses of MA and downplaying any minuses in a manner that is highly misleading, at best. Our concerns include certain revisions to *Medicare & You*, online comparison tools – including the Medicare Plan Finder and associated materials, and education and outreach materials, including an enrollment period email campaign that downplayed, or entirely left out, the option of traditional Medicare. The Center for Medicare Advocacy recently analyzed the 2021 *Medicare & You* handbook, and found that while there have been general improvements in the handbook, bias towards Medicare Advantage remains, and in some ways, has gotten worse. Enrollment in MA plans is promoted at the same time that important restrictions and challenges faced when enrolling in an MA plan are downplayed or omitted.⁸³

In order to resume its critical role as a neutral source of information for the public about Medicare coverage options, CMS must actively and aggressively scrub its resources of this ideological bias towards the private Medicare Advantage program, and engage in future outreach activities with a conscious approach to providing unbiased information. CMS must not only propose, promote and implement policy that addresses the growing imbalance between traditional Medicare and the MA program (including with respect to payment and coverage, as discussed above), it must also support legislation that achieves these goals.

For example, CMS must make clear that people with traditional Medicare can stay put if they wish during the Annual Coordinated Election Period (ACEP), rather than focusing exclusively on “plans” and “plan choices” - and inform people enrolled in MA that they can consider the option of returning to traditional Medicare. Materials meant to provide basic comparison information about traditional Medicare vs. MA coverage must not be incomplete or misleading; such material should not overemphasize the positives of MA enrollment and downplay the negatives. In addition, the positives of traditional Medicare must be clearly stated. We are calling for a return to accuracy in government materials.

⁸² See, e.g., the Center for Medicare Advocacy Weekly Alerts: “Medicare Enrollment Problems Persist” (November 7, 2019), available at: <https://medicareadvocacy.org/medicare-enrollment-problems-persist/>; “Medicare & You 2020 – Better Than Draft, But Room for Improvement” (September 12, 2019), available at: <https://medicareadvocacy.org/medicare-you-2020-better-than-draft-but-room-for-improvement/>; “Improve and Expand Medicare: CMS Should Provide Objective Information About Medicare Options” (February 14, 2019), available at: <https://medicareadvocacy.org/improve-and-expand-medicare-cms-should-provide-objective-information-about-medicare-options/>; “As Medicare Enrollment Period Draws to a Close, MA Steering Continues – Advocates & Members of Congress Write Letters of Concern to CMS” (November 30, 2018), available at: <https://medicareadvocacy.org/as-medicare-enrollment-period-draws-to-a-close-ma-steering-continues-advocates-members-of-congress-write-letters-of-concern-to-cms/>; “CMS Steering to Medicare Advantage” (November 15, 2017), available at: <https://medicareadvocacy.org/alert-tax-cut-harm-just-got-worse-this-week-in-sabotage-cms-pushing-ma-plans-snf-deregulation/#3>; and “You Can Choose Original Medicare: CMS Over-Emphasizes Private Medicare Advantage Plans in Open Enrollment Roll-Out” (October 25, 2017), available at: <https://medicareadvocacy.org/cma-alert-remember-you-can-choose-original-medicare-equitable-relief-this-weeks-sabotage-news/#1>.

⁸³ Center for Medicare Advocacy Weekly Alert “[Medicare & You 2021 – An Assessment of Bias in Favor of Medicare Advantage](https://medicareadvocacy.org/medicare-you-2021-an-assessment-of-bias-in-favor-of-medicare-advantage/)” (September 18, 2020) available at: <https://medicareadvocacy.org/medicare-you-2021-an-assessment-of-bias-in-favor-of-medicare-advantage/>.

Information for Beneficiaries Transitioning to Medicare Coverage

When people become eligible for Medicare they are expected to make consequential decisions about their health insurance coverage that could have significant, negative – and even life-long – consequences. Thus, beneficiaries transitioning into Medicare must be provided with clear, accurate, and timely information about their coverage options and the consequences of their decisions.

As the Center for Medicare Advocacy noted in a letter to Congress supporting the Beneficiary Enrollment Notification and Eligibility Simplification (BENES) Act:⁸⁴

Currently, far too many people make honest mistakes when trying to understand and navigate the complex Medicare Part B enrollment process. The consequences of these missteps can be significant—often leading to a lifetime of higher premiums, substantial out-of-pocket health care costs, gaps in coverage, and barriers to accessing needed services. These lapses in health care coverage and unanticipated financial burdens can swiftly erode a beneficiary’s health and economic security, leading to poorer outcomes and increased costs.

Absent passage of the BENES Act, CMS should do everything in its authority to improve consumer decision-making at this critical juncture, including working with the Department of Labor to improve notices sent to people who elect COBRA coverage from their former employers.

Medicare Plan Finder

As CMS is well aware, in 2019 the agency rolled out a needed update of the Medicare Plan Finder (MPF) platform. Even before being able to test the new platform, advocacy organizations expressed concerns about the timing and manner in which the update was released, which did not give third-party assisters, like State Health Insurance Assistance Programs (SHIPs), adequate time to learn the new tool before Fall Open Enrollment began.⁸⁵ Further, coupled with legislative and regulatory changes that took effect in the 2020 plan year, the truncated MPF launch timeline generated demand for enrollment assistance that these chronically underfunded programs had difficulty meeting.

After the updated MPF was unveiled, and consumers and assisters tried to use it throughout the fall of 2019, errors and inaccuracies became evident. The failure of CMS leadership at the time

⁸⁴ Center letter (June 27, 2019), available at: <https://medicareadvocacy.org/center-letter-in-support-of-legislation-to-help-beneficiaries-make-medicare-decisions/>.

⁸⁵ Center Weekly Alert “Advocates Issue Joint Letter Raising Alarms about New Medicare Plan Finder and Revisions to MA and Part D Marketing Guidelines” (August 29, 2019), available at: <https://medicareadvocacy.org/advocates-issue-joint-letter-raising-alarms-about-new-medicare-plan-finder-and-revisions-to-ma-and-part-d-marketing-guidelines/>.

to acknowledge such errors was problematic, and undermined efforts to educate people about possible relief due to these errors.⁸⁶

We acknowledge the strides that CMS staff have made in improving the updated platform, and efforts to inform stakeholders about pending updates. Going forward, we offer the following recommendations re: the MPF:

- CMS should provide a formal demonstration period for stakeholders, particularly SHIPs and other high-volume assisters, to test the interface prior to open enrollment (beta-testing).
- CMS should provide a mechanism for users to save prescription drug data without creating a MyMedicare account (as allowed in the previous MPF platform prior to Fall 2019)
- CMS should make it clearer and easier to stay in/enroll in traditional Medicare and add a Part D prescription drug plan and/or Medigap plan. This could be accomplished on the Plan Finder tool by linking reminders and choices of Part D and Medigap plans when individuals indicate they are choosing traditional Medicare.

Strengthen State Health Insurance Assistance Programs (SHIPs)

SHIP counselors are essential to helping people with Medicare make informed, individualized choices about how to receive coverage and care, and offer increasingly critical services that cannot be supplied by 1-800 MEDICARE or through web-based and written materials. Rather than cut funding for the SHIP network, as was proposed by the Trump administration, we urge greater investment in this vital, cost-effective program.

Improve Beneficiary Notices

We encourage CMS to continue to develop model notices in consultation with numerous stakeholders, including consumer advocates. Where CMS does not require MA and Part D plans to use model notices, plans should be encouraged to test notices and to report on such testing to CMS. Additionally, CMS should improve communications with individuals with limited proficiency in English.

We urge CMS to require plan sponsors to issue individualized MA and Part D Annual Notice of Change (ANOC) documents to better serve beneficiary needs, specifically one that details which specific providers or pharmacists are leaving a plan network, which specific prescription drugs are no longer on the plan formulary, and where utilization management tools will be newly applied (ideally, reflecting an individual's actual providers, pharmacists, services, and

⁸⁶ See Center statement: "CMS Not Acknowledging Medicare Plan Finder Problems Could Hurt Beneficiaries" (Dec. 2, 2019), available at: <https://medicareadvocacy.org/cms-not-acknowledging-medicare-plan-finder-problems-could-hurt-beneficiaries-full-statement/>.

prescription drugs). CMS should also ensure that MA enrollees who appeal coverage denials receive timely written notices of the decision.

Rescind Recent Updates to Marketing and Communications Guidelines (MCMG)

In recent years, important consumer protections contained in the Medicare Communications and Marketing Guidelines (MCMG) have been stripped. Most importantly, the Center for Medicare Advocacy has significant concerns about the substantive changes⁸⁷ CMS made to the MCMG in 2019 and the manner in which it was done. CMS rescinded important consumer protections from the final 2020 marketing guidelines, without any public comment, resulting in watered down standards. Of note, such changes include blurring the division between educational and marketing events, apparently in conflict with federal law.⁸⁸ As stated in our comments to the proposed 2021 C & D rule, “these revisions appear to violate MIPPA [Medicare Improvements for Patients and Providers Act of 2008]. CMS has an obligation to explain how these revisions do not violate MIPPA. Further, since this was done without public comment, we asked CMS in our comments to disclose from whom they received requests to make these changes, and, if no such requests were made, why the agency did this. We strenuously object to this change, and urge CMS to reverse this end-run around the MIPPA provisions mandating a distinction between marketing and educational events.”

Issue Guidelines re: Plan Information About MA Supplemental Benefits

Current CMS guidance fails to sufficiently address the marketing of MA plans about new supplemental benefits. Clarity on this issue is much needed, given the potential for this expanded authority to create incentives for sponsors to inappropriately steer or target potential enrollees. In failing to update the marketing guidelines to forcefully prohibit these practices, CMS is losing an important opportunity to protect people with Medicare.

The availability of supplemental benefits must not become merely or primarily a sales tool. Sponsors must not be permitted to use supplemental benefits as a marketing device to persuade beneficiaries into their plans. We are especially concerned that agents and brokers may ask individuals about their health status and use that information to steer them toward specific plans in violation of anti-discrimination rules. This guidance continues to do nothing to assuage our concerns. CMS must not enable discriminatory practices through lax oversight, and must ensure that supplemental benefits are actually provided and are of value.

We urge CMS to establish strict rules against targeting certain beneficiary populations and suggest that all shareable information about every plan be made available to potential enrollees,

⁸⁷ See Center for Medicare Advocacy Alert (August 2019): <https://medicareadvocacy.org/advocates-issue-joint-letter-raising-alarms-about-new-medicare-plan-finder-and-revisions-to-ma-and-part-d-marketing-guidelines/>.

⁸⁸ For an extensive discussion of these MCMG changes, see the Center for Medicare Advocacy’s Comments to CMS’ Proposed 2021 C & D Rule (April 6, 2020), available at: <https://medicareadvocacy.org/wp-content/uploads/2020/04/CMA-CD-Comments-2020.pdf>.

empowering them to choose the most appropriate coverage for their unique circumstances. In addition, the roll out of these new benefits must be closely monitored, as even the most thoughtful of policies can have unintended effects. To that end, both CMS and plan sponsors must be vigilant in watching for unusual spikes in enrollment, as well as other patterns that might indicate the existence of inappropriate outreach behavior. Such practices must be reported and corrected when identified.

In various rules and guidance documents, CMS states that “supplemental benefits do not include items or services solely to induce enrollment.” The agency must provide adequate marketing guidelines and oversight to this effect. As discussed further in comments previously submitted to CMS,⁸⁹ we urge CMS to:

- Develop a standardized template for describing additional benefits based on health condition (to be used across the board by plans in EOCs, marketing materials, and in Plan Finder descriptions); and
- Prohibit those marketing plans from engaging/soliciting information about an individual’s health condition(s).

In short, there must be restrictions on how new benefits that are available based on health status/condition are discussed and marketed to individuals. Because such benefits will not be uniformly available to all enrollees, marketing of such benefits should be extremely limited.

5. Actively Work to Enforce the *Jimmo v. Sebelius* Settlement – Require Fair Access to Coverage and Care for People with Chronic Conditions

The Problem: For too long, Medicare beneficiaries have been denied coverage and access to necessary care for which they qualify under the law, based on a long-standing myth that coverage is only available for people who will improve. In 2011 a nationwide class-action lawsuit was brought on behalf of beneficiaries with longer term, debilitating, and chronic conditions to challenge these illegal denials. (*Jimmo v. Sebelius*, (D. Vt., 2013; 2017). The *Jimmo* plaintiffs were represented by the Center for Medicare Advocacy and Vermont Legal Aid.) The *Jimmo* case was settled with CMS in 2013. The Settlement Agreement confirmed that **Medicare coverage is determined by a beneficiary’s need for skilled care, not on a beneficiary’s potential for improvement. Medicare coverage is available for skilled care to maintain or slow decline of an individual’s condition. Improvement is not required.**

Unfortunately, many beneficiaries are still denied Medicare and access to necessary skilled care based on some variation of an “Improvement Standard.” CMS is failing to ensure that the *Jimmo* Settlement Agreement is being properly implemented. The inadequate education of Medicare representatives, contractors, and providers about the Settlement results in continuing harm to Medicare beneficiaries in need of maintenance nursing and/or therapy services who continue to be improperly denied access to appropriate Medicare coverage and care. Too often, when care is is

⁸⁹ See, e.g., Center for Medicare Advocacy comments to CMS on MCMG (April 2019) available at: <https://www.medicareadvocacy.org/center-comments-on-medicare-marketing-guidelines/>.

provided, the costs are inappropriately shifted to beneficiaries, families, and state Medicaid programs.

The *Jimmo* Settlement confirmed that **Medicare coverage is determined by a beneficiary's need for skilled care, not on a beneficiary's potential for improvement. Medicare coverage is available for skilled care to maintain or slow decline of an individual's condition. Improvement is not required.**

Jimmo applies to all Medicare beneficiaries throughout the country, regardless of whether an individual is in traditional Medicare or has a Medicare Advantage plan.

Because of the Settlement, Medicare policy now clearly states that coverage:

[D]oes not turn on the presence or absence of a beneficiary's potential for improvement, but rather on the beneficiary's need for skilled care. Skilled care may be necessary to improve a patient's condition, to maintain a patient's current condition, or to prevent or slow further deterioration of the patient's condition.⁹⁰

Nonetheless, unlawful Medicare denials continue and Medicare decision-makers and providers espouse ignorance about the *Jimmo* Settlement and Court Rulings. Indeed, according to the Center's 2018 national survey of providers⁹¹, 40% of respondents had not heard about the *Jimmo* Settlement and 30% of respondents were not aware that Medicare coverage does not depend on a beneficiary's potential for improvement.

Medicare representatives, contractors, and providers require ongoing education and oversight about the *Jimmo* Settlement in order to avert continuing, avoidable harm to Medicare beneficiaries in need of skilled maintenance care.

Administration Action Needed

In order to ensure that the *Jimmo* settlement is properly implemented so that inappropriate denials due to an improper "improvement standard" cease, CMS must:

- Ensure CMS, its contractors, adjudicators, and providers are active partners in implementing the *Jimmo* Settlement.
- Require CMS to provide at least one training annually regarding the *Jimmo* Settlement for all contactors, adjudicators, and providers.
- Ensure Medicare providers know about the *Jimmo* Settlement, and provide appropriate access to coverage and care for people who need care to maintain their condition or slow decline, as authorized by law and confirmed by the court in *Jimmo v. Sebelius*.

⁹⁰ CMS Transmittal 179, Pub 100-02, 1/14/2014: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R179BP.pdf>

⁹¹ See: <https://medicareadvocacy.org/center-for-medicare-advocacy-survey-cms-jimmo-v-sebelius-improvement-standard-education-still-not-working/>.

- Monitor providers, contractors, and adjudicators at all levels of decision-making and appeals to ensure people who meet *Jimmo* criteria have appropriate access to coverage and care.
- Ensure CMS online and written materials and oral scripts recognize that Medicare can be available for necessary care to maintain an individual’s condition or slow decline, and that improvement is not a prerequisite to coverage.

6. Cover Medically Necessary Oral Health Care

The Problem: Oral health/dental care is increasingly recognized as key to overall health. Unfortunately, CMS recognizes, but significantly limits, Medicare coverage for medically necessary oral health/dental services. While the Medicare Act excludes coverage for “routine” dental services, the exclusion should not be broadly construed to preclude coverage for oral health procedures in all circumstances; this was not the legislative intent. Medicare coverage for medically necessary oral health care is supported by the Medicare statute, its legislative history, CMS policy, and precedent established by Medicare coverage for podiatry services.

The following is excerpted from a document posted on the Center for Medicare Advocacy’s website entitled “*Legal Memorandum: Statutory Authority Exists for Medicare to Cover Medically Necessary Oral Health Care.*”⁹²

Medicare coverage for medically necessary oral health care is supported by the Medicare statute, its legislative history, Centers for Medicare and Medicaid Services (CMS) policy, and precedent established by podiatry coverage. For this purpose, “medically necessary oral health care” refers to care that, according to accepted standards of practice, is reasonable, necessary, integral, and prudent to the management and/or treatment of a covered medical condition, and/or for prevention of a medical complication from oral/dental pathologies.

The Medicare Oral Health Exclusion is Limited and Should be Interpreted Narrowly

The Medicare statute excludes payment for services “in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth...” Section 1862(a)(12) of the Social Security Act [42 U.S.C. § 1395y(a)(12)]. The provision bars payment when the *primary* purpose of the oral health work is to address the teeth and supporting structures.

Importantly, the plain language of the statutory provision does not prohibit payment for oral health services needed “in connection with” treatment of medical issues that extend beyond the teeth and supporting structures. For example, clinical standards and protocols for certain covered medical procedures (e.g., some organ transplants, cardiac surgeries, chemotherapies) require that dental infections be treated to reduce the risk of serious and costly complications.

⁹² This memo is available at: <https://medicareadvocacy.org/medicare-info/dental-coverage-under-medicare/>.

Moreover, the legislative history reflects Congress' intent to limit the dental exclusion to *routine* oral health care. Medicare Part B covers "medical and other health services," 42 U.S.C. § 1395k(a)(2)(B), including "services and supplies ... furnished as an incident to a physician's professional service," *id.* § 1395x(s)(2)(A), and that are "reasonable and necessary," *id.* § 1395y(a)(1)(A). Under this governing framework, coverage would only be available for items and services associated with the diagnosis and treatment of medical illness, injury, and disease. Hence, the coverage exclusions listed under § 1395y(a) are items and services generally considered routine, cosmetic, supportive, preventive, comfort-related, or associated with the normal course of aging.

The Senate Report accompanying the legislation, however, expressly qualifies the scope of these exclusions:

"Payments would not be made for routine physical examinations or for eyeglasses, hearing aids, or the fitting expenses or other costs incurred in connection with their purchase. The committee bill provides a specific exclusion of *routine* dental care to make clear that the services of dental surgeons covered under the bill are restricted to complex surgical procedures. Thus, payment *would* be made under the supplementary plan for the physician's services connected with the diagnosis of a specific complaint and the treatment of the ailment, but a *routine* annual or semiannual checkup would not be covered. Similarly, the diagnosis and treatment by an ophthalmologist of, say, cataracts *would* be covered but the expenses of an eye examination to determine the need for eyeglasses and charges for prescribing and fitting eyeglasses or contact lenses would not be covered. Similarly, too, *routine* dental treatment — filling, removal, or replacement of teeth or treatment of structures directly supporting teeth — would not be covered." S. Rep. No. 89-404 (1965), *reprinted in* 1965 U.S.C.C.A.N. 1943, 1989-90. Emphasis added.

The full section of the Senate Report repeatedly acknowledges there could be clinical situations in which an excluded item or service is medically necessary (i.e., not merely routine, cosmetic, comfort-related, etc.) and clarifies firmly that coverage would be available in those instances.

Medicare coverage for medically necessary oral procedures is further supported by the fact that the statute has always defined "physician" to include dentists. See 42 U.S.C. § 1395x(r)(2).⁹³ Later, Congress even expanded that definition, "when used in connection with the performance of any function or action, [to mean] ... (2) a doctor of dental surgery or of dental medicine ... who is acting within the scope of his license when he performs such functions."⁹⁴ Notably, the House Report to that amendment reinforced that the dental exclusion only applies to "routine dental services."⁹⁵

⁹³ Of note, although this subsection qualifies the scope of actions performed by doctors of podiatry, optometry, and chiropractor, see 42 U.S.C. § 1395x(r)(3)-(5), it places no similar restrictions on the actions of dentists that may be covered. *Id.*, § 1395x(r)(2).

⁹⁴ Pub. L. No. 96-499, § 936(a), 94 Stat. 2599, 2639-2640 (1980) (amending 42 U.S.C. § 1395x(r)).

⁹⁵ H.R. Rep. No. 96-1167 at 372 (1980), *reprinted at* 1980 U.S.C.C.A.N. 5526, 5735.

Accordingly, the dental /oral health exclusion should not be broadly construed to preclude coverage for dental procedures in all circumstances, as this was not the legislative intent.⁹⁶ A narrower interpretation also aligns with Medicare’s fundamental, remedial purpose to help beneficiaries access and afford treatment for major medical problems.⁹⁷

CMS Recognizes But Significantly Limits Coverage for Medically Necessary Dental /Oral Health Services

Dispelling any concern that CMS lacks authority to cover medically necessary dental/oral health services, the Agency has already exercised such authority by permitting Medicare payment for an oral or dental examination prior to kidney transplant surgery. As explained, the statutory exclusion does not prohibit coverage in this instance since the “purpose of the examination is not for the care of the teeth or structures directly supporting the teeth. Rather, the examination is for the identification, prior to a complex surgical procedure, of existing medical problems where the increased possibility of infection would not only reduce the chances for successful surgery but would also expose the patient to additional risks in undergoing such surgery.” Medicare National Coverage Determination Manual (MNCDM) Pub. 100-03, Ch. 1, Part 4, § 260.6.

Consistent with this, the agency also construes the general dental exclusion as reserving payment for the services of dentists “to those procedures which are not *primarily* provided for the care, treatment, removal, or replacement of teeth or structures directly supporting the teeth.”(Emphasis added). Medicare General Information, Eligibility and Entitlement Manual, Pub. 100-01, Ch. 5, §70.2. Based on this accurate understanding of the exclusion’s limited scope, the agency could authorize coverage in a broader range of clinical contexts where dental/oral health treatment is medically required.

Finally, the statute allows payment for dental /oral health services “furnished as an incident to a physician’s professional services” 42 U.S.C. § 1395x(s)(2)(A). CMS has interpreted the provision in conjunction with the dental exclusion to cover a dental procedure performed incident to and as an integral part of a primary, covered *non-dental* procedure. MBPM (Medicare Benefits Policy Manual), CMS Pub. 100-02, Ch. 15, § 150.

However, the Agency has also adopted a policy that requires the dental service to be performed *at the same time as and by the same dentist* who performs the non-dental procedure. *Id.* Under this exacting test, coverage for the dental service is granted in very limited circumstances (i.e., contemporaneous with covered jaw surgery or tumor removal). The “same time/same dentist rule” is viewed by many as unduly restrictive, as well as flawed from a clinical perspective. The rule hinges coverage on the timing of the dental procedure, who administers it, and the anatomical location of the primary covered procedure, rather than taking into account clinical

⁹⁶It is noteworthy that the agency’s original regulation barred payment for “*Routine* dental services in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth.” 20 C.F.R. § 405.310(i), added 31 F.R. 13534, 13535 (Oct. 20, 1966).

⁹⁷ “The Medicare statute, remedial in nature, is to be broadly construed.” Hirsch v. Bowen, 655 F. Supp. 342, 344 (S.D.N.Y., 1987) (citing Gartman v. Secretary of U.S. Depart. Of Health and Human Services, 633 F. Supp. 671, 679 (E.D.N.Y., 1986). Moreover, “exclusions from coverage should be narrowly construed lest they inadvertently encompass the qualifications for benefits.” Westgard v Weinberger, 391 F. Supp. 1011, 1019 (NDND 1975) (citing Coe v. Secretary of Health, Educ. and Welfare, 502 F.2nd 1337, 1340 (4th Cir. 1974).

standards and protocols and whether the procedure is, medically-speaking, incident to and an integral part of a covered medical procedure or course of treatment.⁹⁸

CMS correctly discerned the need to depart from its own rule when it exercised its authority to cover tooth extractions to prepare the jaw for radiation treatment of neoplastic disease. MBPM, Ch. 15, § 150. The logical justification for this coverage is that the tooth extractions are incident and integral to the covered radiotherapy, notwithstanding that the procedures are performed at separate times and by different types of practitioners. The Agency could similarly recognize and authorize coverage in other instances where dental services are unequivocally integral to a covered medical treatment or procedure.

CMS Precedent for Coverage of Medically Necessary Oral Health and Dental Care Exists in the Coverage of Medically Necessary Routine Foot Care

As set forth in 42 U.S.C. § 1395y(a)(13) – a provision listed directly after the dental exclusion in the Act– the Medicare program expressly bars payment for “routine foot care (including the cutting or removal of corns or calluses, the trimming of nails, and other routine hygienic care).” However, CMS does not interpret this statutory exclusion as preventing its coverage of medically-necessary routine foot care.

In its implementing regulation, CMS permitted exceptions for the treatment of warts and mycotic toenails, and for routine foot care if furnished “[a]s an incident to, at the same time as, or as a necessary integral part of a primary covered procedure performed on the foot” or “[a]s initial diagnostic services (regardless of the resulting diagnosis) in connection with a specific symptom or complaint that might arise from a condition whose treatment would be covered.” 42 C.F.R. § 411.15(1)(2).

In interpreting its regulation, the agency’s policy guidance goes even further to authorize Medicare payment for routine foot care when “[t]he presence of a systemic condition such as a metabolic, neurologic, or peripheral vascular disease may require scrupulous foot care by a professional that in the absence of such condition(s) would be considered routine (and therefore, excluded from coverage).” MBPM, Ch. 15, § 290. The policy thus establishes a presumption of coverage when there is documented evidence that a patient has an underlying systemic condition with severe peripheral involvement. Such clinical findings would validate the administration of medically reasonable and necessary, and therefore reimbursable, foot care.

Similar to the exceptions carved out for foot care, CMS could duly establish exceptions to the dental exclusion based on substantiated medical need. As with the foot care exceptions, the policy could provide a non-comprehensive list of underlying conditions that might justify

⁹⁸ See *Lodge v. Burwell*, 2016 WL 7493954 (D. Conn. 2016) (cautioning against “a too-literal application” of the incident-and-integral exception to require that services be performed by the same doctor and on the same occasion. The decision states that a strict application of the same-time/same-dentist rule “is not compelled by the language of the Act and could under certain circumstances lead to results at odds with the purpose of the Act...” It further suggests that the strict requirements of this rule “stand in tension” with the remedial ends of the Act, which would “permit payment for dental services whose primary purpose is not merely the care or treatment of teeth.”).

coverage, and include a rubric of pertinent clinical findings that would support medical necessity.

There Is Precedent for Covering Similar Non-Routine Care

Medicare can be improved by providing medically necessary coverage to address oral health and dental conditions that pose a serious risk to a patient's health or medical treatment. This includes instances where a physician has determined that a patient's oral infection or disease will delay or prevent the receipt of, or otherwise complicate the outcome of, a covered treatment for an underlying medical condition. For example, clinical standards and protocol may strongly recommend or absolutely require the resolution of oral infections for certain patients with diabetes, or pulmonary disease, or who need an organ transplant, immunotherapy, joint replacement, or heart surgery. Untreated oral and dental conditions in such contexts can prove to be not only medically hazardous to patients, but also very costly for the health care system.

As discussed above, CMS has already exercised its authority to cover medically necessary oral health and dental services in a few instances as a matter of policy. The agency does not view the statutory dental exclusion as a barrier to coverage in these instances because the services are not primarily to care for the teeth, but incident and integral to a covered medical procedure. By the same regard, the agency could authorize meaningful coverage for dental services in a broader range of clinical circumstances, much like it did for foot care. Revising CMS policy to define coverage for medically necessary oral and dental therapies would not expand coverage beyond what the Medicare statute allows. To the contrary, it would uphold the general statutory exclusion of basic, routine dental care while fulfilling Congress' goal of ensuring access to and coverage of medically necessary treatment for major health problems.

7. Additional Areas of Concern

a. Improve Part D Coverage and Appeals

Part D Exceptions and Appeals – Improve Consumer Protections

The multi-level, protracted Part D exceptions and appeals process is onerous and time-consuming for Medicare beneficiaries, pharmacists, and prescribing physicians and often significantly delays access to necessary medications. Many Part D enrollees are unaware of both their right to appeal and how to go about initiating the appeals process. Further, Part D enrollees are not provided individually-tailored information when refused a medication at the pharmacy counter, and such refusal does not trigger an appeal. This set up results in considerable time and effort on the part of the beneficiary and his/her physician trying to obtain enough information to affirmatively file an appeal, while many individuals who are denied at the pharmacy counter simply give up. We recommend the following improvements to the Part D exceptions and appeals process.

Individually-Tailored Notice at Pharmacy Counter

When a medication is denied, require that Part D plans provide beneficiaries with an individually-tailored notice that explains the reason behind the drug denial, as is required in the Medicaid program. We believe that access to information about the reason for a plan denial—provided at the pharmacy counter—will both eliminate significant beneficiary confusion and limit delays in accessing needed medications. Armed with information about why a prescription drug was refused at the pharmacy counter, Part D enrollees and their providers will be better equipped to determine the best course of action for the beneficiary’s health.

Denial at Pharmacy Should Trigger Appeal

Along these same lines, we strongly support allowing the pharmacy counter refusal to serve as the coverage determination by the Part D (or Medicare Advantage-Prescription Drug) plan. This proposal serves the dual purpose of removing a burdensome step for beneficiaries and their prescribers, first, by explicitly stating why the drug is not covered and, second, by expediting the appeals process for those who need it.

Allow Tiering Exceptions for Specialty Tier Drugs

Tiering exceptions are currently not allowed for medications on the specialty tier—despite the fact that these are among the costliest medications, making them unaffordable for many beneficiaries with fixed incomes and limited resources. We strongly support the establishment of a cost-sharing exception and appeal process for drugs included on the specialty tier, both as a matter of fairness and to promote affordable access to high-cost medications.

Use Part B Standards for Part D Off-Label Usage

In order to be covered under Part D, drugs must be prescribed for a “medically accepted indication,” meaning their use for a particular disease must be approved by the FDA, or supported by one of three largely inaccessible Compendia, identified at Section 1927(g)(1)(B)(i) of the Social Security Act. (The Act was subsequently modified to allow coverage of anti-cancer drugs if their use is supported in peer review journals.) Under Part B, however, all drugs, not just those used in an anti-cancer regimen, may be supported by peer reviewed literature.

This inconsistency with standard practice of many other insurers (including private insurance and state Medicaid programs) has created serious barriers to access to effective and sometimes life-saving prescription drugs and has been a source of frustration to providers and beneficiaries alike. We recommend that the Part D program align with current standards of “medically accepted indication” currently applicable to Part B.

b. Address Flaws in the Medicare Appeals System

Expedited v. Standard Appeals

Among Medicare beneficiaries, and many advocates, there is lingering confusion in traditional Medicare about the distinction between expedited appeals vs. standard appeals. Expedited

appeals are available for discharge/terminations in Part A from hospital, skilled nursing facility, home health and hospice, and address whether the provider's termination of Medicare-covered services was proper. Standard appeals address whether any *subsequent services* the beneficiary chose to receive are coverable by Medicare.⁹⁹

The lack of clarity in current Medicare publications and notices regarding the difference between expedited and standard appeals has created much confusion among Medicare beneficiaries and representatives. Further adding to the confusion is the fact that Medicare contractors, Administrative Law Judges (ALJs), and the Medicare Appeals Council do not address this issue consistently. Without clear-cut information, a Medicare beneficiary can unknowingly lose his/her right to appeal.

In short, people who pursue expedited appeals beyond the first 2 levels understandably assume that if they continue to receive services (for which they likely pay out of pocket) the ALJ hearing, which is not held on an expedited basis, will address services received subsequent to the discharge termination. In an expedited appeal, however, the lower review levels only look at the decision to terminate coverage, and not whether any services provided thereafter were reasonable and necessary. The termination of coverage claim is considered independent of a claim for coverage of subsequent services received. Therefore, the services provided to the beneficiary post-termination of coverage are new claims that cannot properly be added to a review of the termination itself.

We assert that more effective notice and beneficiary communication about the limited scope of expedited appeals is needed early on to help avoid confusion. Beneficiaries must be explicitly informed that if they want to pursue Medicare coverage for any services received after the coverage termination date, they need to make sure a claim is submitted to obtain an appealable Medicare determination on those services. Moreover, expedited decisions conveyed orally and/or in writing should reinforce this information, letting beneficiaries know that by appealing an expedited decision they are only appealing the termination decision.

On August 29, 2016 the Center for Medicare Advocacy submitted comments on the Centers for Medicare & Medicaid Services (CMS) proposed rule regarding the Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures.¹⁰⁰ In our comments we specifically raised this issue. In the final rule CMS stated that our concerns were outside the scope of the rulemaking but indicated that they “may take them [our concerns] into consideration when making any future revisions to the provider service termination process.” F.R. Vol. 82, No. 10 page 5014 (January 17, 2017). We urge CMS to do so in the new administration.

⁹⁹ See Center for Medicare Advocacy Alert, “Expedited v. Standard Medicare Appeals: Not Knowing the Difference Could Cost You Your Appeal Rights!”, available at: <https://medicareadvocacy.org/expedited-v-standard-medicare-appeals-not-knowing-the-difference-could-cost-you-your-appeal-rights/>.

¹⁰⁰ The Center's comments are available here: <https://medicareadvocacy.org/center-comments-on-proposed-rule-that-would-significantly-alter-the-medicare-administrative-appeals-process/>.

Strengthen Oversight of Medicare Contractors

The minimal success rate of beneficiaries at the lower level of Medicare administrative appeals has been a long-standing problem.¹⁰¹ These results are so skewed against beneficiaries that the first levels of appeal are actually counterproductive. Rather than providing steps at which beneficiaries can obtain an informal review of their initial determination denials, which is the purpose of these levels, they operate as time and effort-wasting hurdles that have to be endured before a beneficiary has any chance of success, which is at the ALJ level. CMS informally takes the position that the lower level denial rates represent a measure of the accuracy of the initial determination stage; that redetermination and reconsideration serve as quality control mechanisms. To the contrary, since the reviews deny coverage the vast majority of the time, the appeals system simply does not work.

The “success rates” are so ludicrously low as to be no review at all. The irony is that the review process changes made in the last decade or so were supposed to make the lowest levels of review a more efficient and effective part of the process, so that beneficiaries would **not** be forced to go to the ALJ level. Now, with success virtually impossible at the lowest levels of review, beneficiaries **must** continue their appeals to the ALJ level to have any chance of success. As a practical matter, the lowest levels of review now act as an impediment to obtaining any effective review at all.

The appeals process is meaningless unless the BFCC-QIO and other Medicare contractors are actually making fair and informed decisions that are consistent with the law. We urge CMS to conduct meaningful audits and oversight of Medicare contractors that handle the levels of review prior to ALJ hearing.

General Appeals Issues

We urge CMS to ensure greater consistency between traditional Medicare and Medicare Advantage appeals. Unlike in traditional Medicare, in Medicare Advantage cases, a plan enrollee only gets a Notice of Medicare Non-Coverage (NOMNC) and must separately contact the plan to get a standard appeal in the system. This can be cured, in part, by changing the NOMNC so that an MA enrollee knows exactly what steps to take to get a standard appeal in the system.

The Center also strongly urges CMS to reverse the policy changes over the last several years that have made phone hearings the default for Administrative Law Judge (ALJ) hearings sought by parties other than unrepresented beneficiaries, unless an ALJ finds good cause for a video-teleconference (VTC) or in-person appearance. There is no reasonable justification for this change and it has created a significant reduction in due process. Phone hearings do not take appreciably less time than VTC hearings and do not afford the same level of communication. Whatever the advantage of a phone hearing is to the Office of Medicare

¹⁰¹ See, e.g., Center for Medicare Advocacy Alert (April 2015) at: <https://medicareadvocacy.org/senate-finance-committee-holds-hearing-on-medicare-appeals-backlog-proposed-solutions-are-of-great-concern/>.

Hearings and Appeals (OMHA) does not outweigh the value of VTC hearings for beneficiaries. When parties can see one another and exhibits, communication is far better.

The Center has found that appearance by VTC affords greater assurance that ALJs fulfill their duty to provide a full and fair hearing. VTC has allowed us to gauge the ALJs' reaction to arguments, and better ascertain whether there was understanding, confusion or lingering questions. With VTC, we have some awareness when an ALJ is tired, disinterested, talking to someone else in the room, thumbing through the file or not referring to the file at all. This is not readily witnessed on a phone call.

c. Improve Access to Durable Medical Equipment (DME) for Dually Eligible Individuals

We appreciate CMS efforts in addressing the misalignment of payment procedures in Medicare and Medicaid that results in denials, delays, and higher than appropriate health care costs for essential Durable Medical Equipment (DME) among dually eligible beneficiaries. Particularly, we support the CMS bulletins that have encouraged states to adopt strategies to improve dual eligible beneficiaries' access to DME, such as prior authorization.

However, we urge CMS to go beyond this and require state Medicaid programs to prior authorize DME for dually eligible beneficiaries whenever it does so for those who receive only Medicaid. For example, the state of Connecticut has such a requirement, *see* Conn. Gen. Stat. § 17b-281a, and it has dramatically simplified the process of obtaining DME for beneficiaries, and ensured payment for providers, while still complying with the requirement that Medicaid always be the payer of last resort.

Under the long-standing Connecticut statute and process, Connecticut providers know that if Medicare payment is not forthcoming, the existing Medicaid prior authorization means that Medicaid payment will eventually be forthcoming, so they are willing to provide, and then bill Medicare for, equipment that has already been found by the state to be covered under Medicaid and medically necessary for such dually eligible individuals. This process fully complies with the requirement that Medicaid be the payer of last resort because actual Medicaid payment will only be made after Medicare payment is denied. This simple solution reduces burdens on beneficiaries and providers alike. We have outlined these proposals in [letters](#) to CMS over the years.

d. Rescind Final Rule Rolling Back Critical Non-Discrimination Provisions Pursuant to §1557 of the Affordable Care Act

The Center for Medicare Advocacy calls on the Office of Civil Rights (OCR) to withdraw its final rule rolling back critical non-discrimination provisions in health care.¹⁰² The Center for Medicare Advocacy joined many other organizations in [opposing](#) the Administration's efforts to limit the law's protections for sex discrimination that is based on gender identity. This portion of

¹⁰² See Center for Medicare Advocacy Alert: <https://medicareadvocacy.org/gender-identity-discrimination-another-attack-but-also-a-win/>.

the final rule got the most attention because only days after the 1557 final rule was issued, interpreting “on the basis sex” to exclude protections for LGBTQ individuals, the U.S. Supreme Court issued a decision in *Bostock v. Clayton County, Georgia* (June 15, 2020, by a 6-3 majority). The *Bostock* decision holds that discrimination “because of sex” under Title VII of the Civil Rights Act includes, and prohibits, workplace discrimination based on sexual orientation and gender identity.

The Center for Medicare Advocacy strongly supports the outcome in *Bostock* and recognizes that it is an important step in the effort to foster equality and inclusion in our society.

The Center would like to call attention to other harms in the final rule, as it also limits the law’s protections for individuals who have limited English proficiency, LGBTQ persons, and persons with disabilities and chronic conditions, among others.

Due to the nature and importance of health care and the consequences that can result from language barriers, it is especially critical that older adults have robust language access resources and protections from discrimination, can access care and services, receive important healthcare information in a language they understand, and are informed of their rights and how to enforce them.

Due to their age, physical limitations, and other factors, it is unrealistic to expect many limited English Proficient (LEP) seniors to attain full English proficiency.

Visiting health care facilities and agencies that administer health programs and activities are often uncomfortable for individuals with LEP who are “unfamiliar with [the system’s] cultural norms, vocabulary, and procedures.”¹⁰³ Unfamiliarity with the health care system often results in inaction that could compromise a basic standard of living for individuals and families.

Furthermore, the lack of language assistance services negatively impacts communities at large, not just LEP individuals. When interpreter services are inadequate, children often serve as language brokers for their parents.¹⁰⁴

The cost of these barriers to care for individuals with LEP can be deadly.

e. Rescind the Public Charge Rule Which Creates Almost Insurmountable Barriers to Entry into the United States for Older Immigrants

The Center has joined other organizations that advocate for older adults in filing [amicus briefs](#) in several lawsuits challenging the Department of Homeland Security’s “public charge” rule. The regulation, finalized last year, represents a drastic change in how applicants for lawful permanent residency (green cards) will be evaluated, and it will have a particularly negative impact on older

¹⁰³ Vikki Katz, *Children as Brokers of their Immigrant Families’ Healthcare Connections*, at 24 (2014), <https://academic.oup.com/socpro/article-abstract/61/2/194/1672037?redirectedFrom=fulltext>.

¹⁰⁴ *Id.*, at p. 31.

immigrants, including those who are dually eligible for Medicare and Medicaid. Under the rule, use of programs that are often vital to the livelihood of older adults, such as Medicaid, SNAP (food stamps), or housing benefits, could jeopardize the pathway to a green card. The rule would also make being over 62, or having a treatable medical condition, “negative factors” in the public charge determination, and it would impose an arbitrary and unprecedented income test.

While the public charge rule does not involve Medicare itself, the use of Medicaid-funded benefits such as Medicare Savings Programs, which provide critical assistance with premiums and cost-sharing for lower-income Medicare beneficiaries, could weigh against a green card applicant. As the amicus briefs state, the rule “shoves aside existing law and erects new – and often insurmountable – barriers to entry into the United States for older immigrants.”

We urge the incoming administration to rescind this rule.

f. Withdraw/Rescind the Proposed SUNSET Rule that would put an Automatic Expiration Date on Critical Medicare (and Other) Regulations

On November 4, 2020, the Department of Health and Human Services’ (HHS) issued a [proposed rule](#) entitled “Securing Updated and Necessary Statutory Evaluations Timely” (SUNSET) (RIN 0991–AC24; Docket No. HHS–OS– 2020–0012).

The proposed rule would retroactively impose an expiration provision on most HHS regulations, and establish “assessment” and “review” procedures to determine which, if any, regulations should be retained or revised. Regulations would have to be reviewed 2 years after this rule is effective or 10 years after promulgation, whichever is later; regulations that were not reviewed in a timely manner would expire.

Noting that this is an ill-conceived proposal that would create tremendous administrative burden for HHS and would wreak havoc across a broad swath of HHS programs, the Center strongly opposes this rule, and urges HHS to withdraw or otherwise rescind this rule.¹⁰⁵

g. Suspend Direct Contracting Demonstration that Leaves Critical Consumer Protection Issues Unaddressed

As noted in recent releases by CMS, the agency is soliciting participation in the new Geographic Direct Contracting Model (the “Model”) aimed at coordinating care and clinical management for beneficiaries in traditional Medicare in their region.¹⁰⁶ CMS is soliciting letters of interest in

¹⁰⁵ See, e.g., Center for Medicare Advocacy comments to proposed rule: <https://medicareadvocacy.org/comments-on-hhs-regulations-rule/>; also see CMA Weekly Alert: <https://medicareadvocacy.org/center-for-medicare-advocacy-comments-on-harmful-proposed-rule-that-would-automatically-expire-regulations-governing-medicare-and-other-important-programs/>.

¹⁰⁶ See, e.g., CMS’ December 3, 2020 Press Release at: <https://www.cms.gov/newsroom/press-releases/cms-announces-new-model-advance-regional-value-based-care-medicare>; also see, e.g., CMMI website at: <https://innovation.cms.gov/innovation-models/geographic-direct-contracting-model>.

December 2020, the Request for Applications will be made available in January 2021, and Applications will be due on April 2, 2021. Model Participants will be selected by June 30, 2021.

Although CMMI has been developing the Direct Contracting Model over the last couple of years, critical consumer-oriented questions posed at the outset have not yet been addressed. For example, in May 2019 the Center for Medicare Advocacy participated in the public comment process concerning this model,¹⁰⁷ but recent CMS materials still do not answer threshold questions or concerns regarding how this model might work.

For example, unanswered questions include: how will the model coordinate with other insurance an aligned beneficiary may have (e.g., Medigap, employer-based retiree coverage); will there be an equivalent of an MA organization determination provided in order to challenge denials due to prior authorization, which currently does not exist in the traditional Medicare appeals program that aligned beneficiaries will use; what type of notice and education will be provided to aligned beneficiaries; and what, if any, consumer protections applicable in the MA program – such as marketing guidelines – apply to Direct Contracting Entities (DCEs)?

While CMS contemplates participation by health plans, receiving capitated payments and able to employ utilization management such as prior authorization, it appears that such plans would be well compensated but not subject to even the minimal reporting and oversight requirements applicable to Medicare Advantage plans (e.g., medical loss ratio, reporting of encounter data, etc.).

There are too many unanswered questions, and too little appears to be required of DCEs. Instead of rushing to implement this program, set in motion in the waning days of the Trump Administration, we urge CMS to suspend implementation of the Direct Contracting Model.

h. Hold More Frequent Meetings with Advocates

We urge the leadership of HHS in the incoming administration to make an active effort to meet more frequently with organizations representing older adults and individuals with disabilities broadly, and Medicare beneficiaries more specifically. While the Trump Administration offered the opportunity to participate in National Medicare Education Program (NMEP) meetings – which we encourage HHS to continue - meetings with HHS or CMS decision-makers were isolated and sporadic. We are aware that various industry stakeholder groups more regularly met with administration officials about various programmatic concerns. Consumer advocacy groups have valuable input to contribute, and often are able to troubleshoot issues before they become more harmful to beneficiaries. We urge HHS to work with groups individually, and in coalition, including the Leadership Council of Aging Organizations (LCAO).

¹⁰⁷ See the Center's May 2019 comments here: <https://medicareadvocacy.org/center-comments-on-direct-contracting/>.

V. CONCLUSION

The Center for Medicare Advocacy looks forward to working with the Biden Administration. We hope the suggestions in this Memorandum are helpful, and urge HHS to pursue them in order to make the Medicare program stronger, more equitable, and more able to provide access to quality care.

Please contact us if we can provide assistance or to discuss any of these issues further.

Thank you.

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