STATE OF MAINE BOARD OF LICENSURE IN MEDICINE

IN RE:

MERYL J. NASS, M.D. COMPLAINT NOS. CR21-191, CR21-210, AND CR22-4

BOARD STAFF CLOSING ARGUMENT ON ALLEGED VIOLATIONS

This case is about patient care—more precisely, Dr. Nass' failure to provide safe and appropriate care to her patients. This case is about what level of care is owed to patients, what constitutes valid scientific evidence to support patient care decisions, how patient information and care should be tracked and documented when treating high-risk COVID patients even telephonically, and whether a physician must be truthful with other healthcare professionals when communicating about the care she is providing to a patient. As the evidence you heard shows, Dr. Nass repeatedly failed to comply with applicable medical standards and repeatedly violated her duties to her patients. Dr. Nass may argue that this case is about other issues, including disciplining her for expressing her views on social media or in other public forums. Please, do not be distracted by such attempts to divert attention from her own deficiencies. No counts relate to her public communications, and any of Dr. Nass' arguments to the contrary should be disregarded as irrelevant.

Throughout your deliberations, you should be guided by your sole purpose as set out in statute: "to protect the public health and welfare . . . by ensuring that the public is served by competent and honest practitioners . . . and disciplining practitioners" of medicine. 10 M.R.S. § 8008; *see also* 32 M.R.S. § 3269. To assist the Board, we summarize below the evidence that has been admitted relevant to the actual allegations and that proves by a preponderance that Dr. Nass committed these violations. The evidence below is presented in an outline that parallels Sections

A-D of the allegations in the Third Amended Notice of Hearing ("the Notice") contained in the first 3 pages of Staff Exhibit 1. To facilitate and focus your deliberations, we suggest that you print out and have at hand two items: 1) the first 3 pages of the Notice; and 2) the last page of this closing argument, which is a table depicting Dr. Nass' deficient care for each patient.

<u>A. Patient Care and Medical Competence: Counts I, II, IV, V, VI, VIII & IX</u>

There are seven allegations in the Notice that deal directly with how Dr. Nass provided care to her patients: Counts I, II, IV, V, VI, VIII, and IX. Dr. Nass' conduct may implicate each count more than once, as discussed below.

• <u>COUNTS I, II & IV</u>

Count I alleges that Dr. Nass' treatment of Patients 1, 2, and 3 evidenced a lack of ability or fitness to discharge the duty Dr. Nass owed to the patients. **Count II** alleges that Dr. Nass' treatment of Patients 1, 2, and 3 evidenced a lack of knowledge or an inability to apply principles and skills in the practice of medicine. **Count IV** alleges that Dr. Nass' care provided via telemedicine failed to meet the appropriate standard of care.

Dr. Nass committed the violations alleged in Counts I, II, and IV in at least four ways: 1) by prescribing ivermectin or hydroxychloroquine for COVID to the patients; 2) by relying on insufficient scientific evidence to justify prescribing those medications to those patients; 3) by providing subpar patient care to high-risk, at-home COVID patients via telephone or text; and 4) by failing to adequately discuss the risks or benefits of, or alternatives to, the treatments she prescribed.

Dr. Nass' prescribing ivermectin or hydroxychloroquine to treat COVID demonstrated incompetence and failed to meet the standard of care (Counts I, II & IV).

Neither hydroxychloroquine nor ivermectin were scientifically valid COVID treatments during the relevant timeframe of September—December 2021. Dr. Courtney testified that the lack of demonstrated efficacy was well-established by then, as the result of significant early research into these drugs. Tr. 10/25 415:9-12 & 430:19-431:12;¹ & Staff Exs. 30 (Dr. Courtney's expert report) & 30-1 to 30-5 (Courtney sub-exhibits). The FDA's cautionary statement against the use of hydroxychloroquine (Staff Ex. 30-1) is one of the Courtney sub-exhibits that supports Dr. Courtney's conclusion that the lack of efficacy was well-established.

None of the allegations in this case allege violation for off-label prescribing *per se*—the experts agree that off-label prescribing is permissible as a general principle. Rather, the allegations are that Dr. Nass violated the standard of care by prescribing ivermectin to Patients 1 and 2, and hydroxychloroquine to Patients 2 and 3, without valid scientific evidence to support using these medications to treat COVID-19. Dr. Courtney testified that prescribing a medication off-label "entails understanding where the current literature is showing you medication has value." Tr. 10/25 414:24-415:1. Dr. Risch, one of Dr. Nass' experts, agreed that the clinician bears some responsibility to show the possibility of meaningful benefit of an off-label prescription. Tr. 5-30 1193:19-23.

Dr. Courtney opined that the contemporaneous medical literature showed hydroxychloroquine had "no value" and that the ivermectin studies "did not show an effect of the medication." Tr. 10/25 415:12, 426:13-22 & 431:11-12. Dr. Courtney agreed that off-label prescribing is permitted, emphasizing that when prescribing any medication off-label, there must be both evidence to support the efficacy of the medication for the intended purpose, and a compelling reason to use it. Tr. 10/25 413:11-416:24. Both on- and off-label prescribing require that same risk-benefit analysis. *Id.* Dr. Faust agreed. Tr. 5/30 1127:12-18. Dr. Katsis agreed that

¹ The hearing transcripts from the previous days of hearing are cited as follows: "Tr." followed by the date in month/day format, then the page number, colon, followed by the line number(s).

an off-label prescription should be evaluated like any other prescription based on the "merits of the medical judgment and management." Tr. 7/28 1538:8-9.

Dr. Courtney concluded that prescribing hydroxychloroquine to treat COVID-19 in September or December of 2021 did not meet the standard of care because, at that time, it was known that "the medication did not work." Tr. 10/25 427:16-428:1 & 426:4-22; & Tr. 1/31 484:3-10. Dr. Courtney also concluded that prescribing ivermectin to treat COVID in September and December 2021 similarly did not meet the standard of care. Tr. 10/25 430:19-431:12; & Tr. 1/31 461:2-4, 481:3-6 & 481:14-17. Accordingly, Dr. Nass' prescribing of ivermectin and hydroxychloroquine to treat COVID demonstrated incompetence and violated the standard of care.

• Dr. Nass's reliance on inadequate scientific evidence to make treatment decisions demonstrated incompetence and failed to meet the standard of care.

On January 10, 2022, Dr. Nass submitted what she claimed was "evidence" to support her prescribing of ivermectin and hydroxychloroquine Staff Ex. 87 ("Here is the evidence of benefit from 29 early treatment studies using Ivermectin for covid") & Staff Ex. 88 ("Here is a similar compilation of the results of 33 early treatment studies using hydroxychloroquine for Covid.") Both exhibits are simply one-page putative forest plots that list studies purportedly supporting early treatment of COVID with ivermectin ("67% improvement") and hydroxychloroquine. Staff Ex. 87 ("*IVMMETA* graphic") & Staff Ex. 88 ("*HCQMETA* graphic").

Dr. Faust, a Boston emergency room physician, Harvard professor, COVID scholar, and co-editor of a weekly COVID newsletter, testified that in making treatment decisions based on medical literature physicians should "look at that totality of medical evidence . . . to have that medical evidence and scientific basis guide our treatment decisions." Tr. 1/31 657:10-24 & Staff Ex. 32 (Dr. Faust's expert report).

Dr. Faust first testified about the high-quality studies that refuted ivermectin's and hydroxychloroquine's efficacy as COVID treatments. Tr. 3/2 745:7-752:17 & 758:7-759:1; *see also* Staff Exs. 32² pdf 2107-2111 pp. 2112-2117; 32-26; 32-34 & 32-35 (ivermectin ineffective); & Tr. 1/31 659:17-670:8; Staff Exs. 32 pdf 2109-2110 pp. 2115-2116; 32-27 & 32-28 (hydroxychloroquine ineffective). Dr. Faust testified that neither medication met the standard of care and that this was the consensus among reputable medical institutions and professionals. Tr. 3/2 745:1-11 & 758:7-759:1 (ivermectin); Tr. 1/31 672:3-674:6 & 720:1-3 (hydroxychloroquine).

Dr. Faust also assessed both the *IVMMETA* and *HCQMETA* graphics, as well as the exhibits from Dr. Nass' expert, Dr. Risch (Licensee exhibits 151A and 151B). According to Dr. Faust, the websites from which Dr. Nass took the *IVMMETA* and *HCQMETA* graphics are not reliable sources of medical research and their collected studies "are the results of extremely poor, if not abjectly cynical, research methodologies, and are only convincing to amateurs." Staff Ex. 32 pdf 2108-2109 pp. 2114-2115; *see also* Tr. 1/31 678:11-17. Dr. Faust detailed numerous methodological deficiencies among even the scientifically higher-quality studies listed in the *IVMMETA* and *HCQMETA* graphics, and further identified multiple reasons why the listed studies could not be validly cited to support the claimed conclusion that either drug was effective for early treatment of COVID. Tr. 3/2 763:8-790:25 & Staff Exs. 32, 32-34, & 32-36 –32-40 (ivermectin); Tr. 1/31 687:21-703:12 & Staff Exs. 32 & 32-29 to 32-33 (hydroxychloroquine). One particular concern Dr. Faust highlighted was invalid reliance on secondary research outcomes to support clinical decisions about patient care. Dr. Faust testified that secondary

² Staff exhibit citations refer to both the pdf page numbers for the electronic exhibits and the Bates stamp page numbers for the printed version of Staff exhibits. The citations will include Staff Ex. number, pdf page number, and Bates page number in this format: Staff Ex. 21 pdf 231 p.230.

outcomes are properly used solely to generate hypotheses for further research and are not valid bases for patient care decisions. Tr. 3/2 768-769, 774:10-18 & 775. Dr. Risch held the opposite view, indicating he could choose his own primary outcomes from other researchers' studies, "the study was cited by me, by me. And so for me, it's a primary outcome." Tr. 5/30 1241:20-22. When asked to refute Dr. Faust's conclusion that Dr. Nass' prescribing based on the *HCQMETA* graphic evidenced a lack of fitness or inability to discharge the duty owed to a patient, Dr. Risch aptly testified "I don't think I have enough clinical expertise to be able to judge that question fairly." *Id.* at 1257:4-5

Dr. Faust reviewed in detail two exhibits Dr. Risch prepared, the first about ivermectin's efficacy to prevent COVID infection (Licensee Ex. 151A), and the second about hydroxychloroquine's safety and efficacy as a COVID early treatment (Licensee Ex. 151B). Dr. Faust concluded that Exhibit 151A involved similar deficiencies to those in the IVMMETA and HCOMETA graphics (Tr. 3/2 791:3-804:15), which websites Dr. Risch admitted he considered reliable resources and used them in part to create these exhibits. Tr. 5/30 1209:6-12. As a result of the deficiencies Dr. Faust identified, he concluded that Dr. Risch's paper about ivermectin (151A) did not lead to a valid conclusion on which a reasonably prudent practitioner could rely in making treatment decisions. Tr. 3/2 791:1-805:3. Dr. Faust further testified about the methodological problems in Exhibit 151B and concluded that, like the other evidence Dr. Nass submitted, Exhibit 151B failed to establish any valid support for hydroxychloroquine's efficacy for treating COVID. Tr. 1/31 713:17-718:8 (describing the studies relied on as "unreliable" and "[r]eally low quality," Dr. Risch's analysis as "erratic," and the methodology as "completely left to our imaginations"). Dr. Risch's exhibits relied on many of the same studies contained in Dr. Nass' HCOMETA and IVMMETA graphics. Compare Licensee Ex. 151B, with Staff Ex. 88 &

compare Licensee Ex. 151C, *with* Staff Exs. 87 & 88. Dr. Risch testified he created Licensee Exs. 151B and 151C at the request of Dr. Nass' counsel for this case (Tr. 5/30 1229:11-18), and that only one of them was posted to the the public. Ex. 151B was posted on a COVID website, which Dr. Risch explained "is not a clinical care website" and described as only informational. Tr. 5/30 1177:20-24. Dr. Risch did not indicate either of these exhibits had undergone any level of scientific or peer review.

Ultimately, Dr. Faust concluded that a reasonably prudent practitioner would not prescribe either ivermectin or hydroxychloroquine based on the studies Dr. Nass submitted in the *IVMMETA* and *HCQMETA* graphics. Staff Ex. 32 pdf 2114 p. 2121; Tr. 3/2 748:23-779:11 (refutations of selected *IVMMETA* studies); & Tr. 1/31 675:18-718:21 (refutations of selected *HCQMETA* studies).

Related to **Counts I & IV**, Dr. Faust concluded that Dr. Nass' reliance on the studies listed in the *IVMMETA* graphic evidenced a lack of ability or fitness to discharge the duty Dr. Nass owed the patients, "because it was done in the context of not referring patients to an appropriate level of care." Tr. 3/2 805:4-17. When cross-examined, Dr. Faust also testified that "neither medication is evidence-based standard of care." Tr. 5/30 1122:20-24 (referring to ivermectin and hydroxychloroquine); *see also, id.* at 1071:23-25 & 1087:16-23 (hydroxychloroquine not standard of care). Finally, on cross-examination, Dr. Faust contested Dr. Nass' hypothetical that a physician could prescribe hydroxychloroquine on the sole bases that the physician judged the medication appropriate and the patient had given informed consent, because in Dr. Faust's opinion those two factors could not substitute for the evidence-based standard of care, including referral to the appropriate level of care when necessary. Tr. 5/30 1124:18-25.

Related to **Counts II & IV**, Dr. Faust concluded that Dr. Nass' reliance on the *IVMMETA* graphic studies as the basis for treating COVID patients with ivermectin evidenced a lack of knowledge or inability to apply principles because "one of the important things that a physician does is to integrate medical research into clinical decision-making and so this evidences an inability or unwillingness to do that." Tr. 3/2 806:19-807:7. Regarding prescribing hydroxychloroquine based on the studies in *HCQMETA* graphic, Dr Faust testified that because Dr. Nass provided these studies to the Board "Dr. Nass is telling us she prescribed these treatments based on a reading of literature and data," and that Dr. Nass did not interpret that data correctly, which "demonstrated a lack of fitness in doing something that I think is very important which is to interpret medical literature when making treatment decisions." Tr. 1/31 721:18-722:14.

• Dr. Nass' at-home Care of Patients 1, 2, & 3 Demonstrated Incompetence (Counts I, II & IV):

Beyond the medications prescribed, Dr. Courtney testified that the individual care Dr. Nass provided to Patients 1, 2, and 3 substantiated **Counts I, II & IV.** Testimony indicated Dr. Nass was the sole COVID medical provider for Patients 1 and 2 prior to hospitalization. The records and testimony establish that Patients 1, 2, and 3 were each at high risk of developing a severe case of COVID-19, which could result in death or long-term respiratory debility. Tr. 10/25 431:13-16 & Tr. 1/31 455:11-16, 479:6-16, 501:25-502:6. Dr. Courtney testified that patients with COVID-19 can rapidly worsen and that the main cause of death from COVID-19 is hypoxic respiratory failure. Tr. 1/31 470:7-9. Dr. Courtney testified "[i]t is essential be certain as to the progress of the disease" when treating COVID patients. Tr. 1/31 470:6-7. To meet the standard of care, Dr. Courtney stated when treating at-home COVID patients a physician must regularly gather, track, and record relevant symptoms to properly assess the state of the patient, evaluate the progression of the disease, and determine when escalation of care is required for the patient's safety. *E.g.*, Tr. 10/25 407-408. Relevant symptoms include respiratory rate, presence of tachycardia (elevated heart rate), dizziness, ability to stand, difficulty or discomfort breathing, shortness of breath, cognitive function, confusion, heart rate, ability to ambulate, and ability to care for themselves. *Id.* at 408:9-16; & Tr. 1/31 469:3-8 & 498:18-499:3. The evidence clearly shows that Dr. Nass failed to properly gather, track, or record any of this information. Thus she failed to meet the standard of care.

Patient 2 At-home Care

Dr. Nass' treatment of Patient 2 is addressed first because the care of this patient raises the most serious issues, including the failure to refer to acute care when it was clearly needed. Dr. Nass' at-home care of Patient 2 demonstrated incompetence and failed to comport with the standard of care (**Counts I, II & IV**). Dr. Nass also failed to refer Patient 2 to acute care immediately when that care was needed (**Count VIII**). According to Dr. Courtney, Patient 2 was "right at the edge of dying" (Tr. 1/31 487:1-11) and Dr. Nass failed to appreciate that fact and failed to immediately refer Patient 2 to urgent or emergent care.

Patient 2 first showed COVID symptoms on either Monday, December 6th, 2021 (Tr. 7/28 1409:18-20) or Tuesday, December 7th (Staff Ex. 21 pdf 237 p. 236 ("First sx last Tuesday" refers to December 7, 2021)). Patient 2's wife contacted Dr. Nass on December 11th. *Id.* at pdf 234 p.233. Dr. Nass' notation of the call records only a plan, including reduction of diltiazem, prescribing hydroxychloroquine and azithromycin, and instructions for the patient to call in three weeks. *Id.* at pdf 233 p. 232. Patient 2 testified that from the onset of his symptoms through the early part of his hospital stay he had memory issues and confusion, which he did not know whether to attribute to COVID, low oxygenation levels, or the fever he experienced. Tr. 7/28

1353:17-25. Nothing in Dr. Nass' records indicates that she ever inquired about or documented Patient 2's mental state or confusion. Staff Ex. 21. Patient 2 said that his breathing was impacted within a few days from the onset of COVID and that his pulse oxygen levels trended downward over time. Tr. 7/28 1358:6-14. Patient 2 testified that by the time his pulse oxygenation levels were below 90 percent he was having difficulty breathing. *Id.* at 1382:9-11. Dr. Nass made no notation of Patient 2's breathing difficulties or how any respiratory symptoms progressed. Staff Ex. 21.

Patient 2 testified that he had no knowledge whether Dr. Nass consulted the prescriber of his diltiazem. Tr. 7/28 1380:13-1381:4. Dr. Nass' patient care expert, Dr. Marik, testified generally that consultations with a patient's specialists don't happen "in the real world" but acknowledged "there may be a specific reason" to consult a prescribing physician. *Id.* at 1493:22-1495:2. Dr. Courtney disagreed, testifying that it was "[a]bsolutely not" typical to adjust a medication like diltiazem without consulting the primary treating physician, who would have the relevant knowledge base. Tr. 1/31 482:24-483:9. Dr. Courtney explained "[t]here may be particular reasons why the dose prescribed is what it is and to alter that in absence of knowledge of the primary care physician is – is not appropriate." *Id.* at 483:9-13.

Dr. Nass' medical records for Patient 2 refer to his COVID symptoms during at-home care only twice: first, on the afternoon of December 15th in a text message and second, on the phone slip of the telephone call that evening. Staff Ex. 21 pdf 233 & 231 pp. 232 & 230. On two consecutive days, December 14th, and December 15th, 2021, Patient 2's pulse oxygenation levels fell to 88 or 89 percent. *Id*. Dr. Courtney testified his symptoms meant Patient 2 was "desaturating. He's got severe hypoxic respiratory failure." Tr. 1/31 487:1- 2. Patient 2 was "right at the edge of dying from COVID." *Id*. at 487:8. Dr. Courtney stated that "[p]eople in

hypoxic respiratory failure at this point can quickly progress and die from the disease." Id. at 487:9-11. Seemingly oblivious to the seriousness of low oxygenation, Dr. Nass testified that she thought pulse oxygenation levels below 90 percent were "pretty common" for COVID patients. Tr. 10/25 371:16-20. Dr. Courtney, however, was adamant that the patient's hypoxia, combined with the patient's tachycardia was "critical." Tr. 1/31 488. "He needs to be in the hospital frankly." Id. at 488:11-12. Dr. Courtney stated Patient 2 "[s]hould have been sent to the emergency department or EMS should have been called" as soon as Dr. Nass first learned that Patient 2 had been hypoxic and tachycardic. Id. at 488:17-21. When Patient 2's hypoxia was again reported to Dr. Nass during the 7:30 p.m. phone call, Dr. Courtney testified that a reasonably prudent physician would have sent the patient to the emergency department. Id. at 490:16-20. Where Patient 2 had been hypoxic on two consecutive days, Dr. Courtney concluded he was "failing, he's got hypoxic respiratory failure, it's not getting better, he's on a progressive course of disease and needs to be in an emergency department, needs to be admitted." Id. at 491:4-7. When asked if Dr. Nass had testified that oxygen saturation below 90 percent is nonemergent, Dr. Courtney opined "[t]hat's just so false. It demonstrates significant hypoxic respiratory failure." Id. at 491:12-14. Dr. Courtney was unequivocal about Patient 2's state on December 14th and 15th and that his symptoms required immediate referral to acute care. Dr. Marik testified that Dr. Nass did not delay Patient 2 going to the ER, because the official NIH stance was "stay at home until you go blue and you can't breathe." Tr. 7/28 1496:13-25. However, Dr. Marik did not opine about whether Patient 2's actual symptoms as reported to Dr. Nass warranted referral to acute care.

Dr. Nass testified that even on the evening of December 15th, "it didn't sound like he was sick enough that he would be admitted." Tr. 10/25 373:14-15. Dr. Nass testified that the message

she wanted to convey that evening was "don't worry, don't worry so much." *Id.* at 374:3-4. Finally, Dr. Nass testified "I didn't advise it [acute care] earlier because I didn't think he was sick enough to need it and he hadn't had the benefit of the Hydroxychloroquine which I thought would sort of maybe even double the efficacy." *Id.* at 387:3-7.

Patient 2 testified that he credited Dr. Nass with recommending the chest x-ray. But when asked "if Dr. Nass had told you or your wife directly on the night of December fifteenth that you needed to go immediately to the emergency department at the hospital, would you have done that?" Patient 2 testified "Yes, I'm sure we would have." Tr. 7/28 1386:16-21. Again, Dr. Courtney's expert opinion was unequivocal: rather than make suggestions about diagnostic tests like a chest x-ray, the medical advice to the patient "should have been go to the emergency department." Tr. 1/31 493:23-25.

Related to **Counts I, IV & VIII**, Dr. Courtney concluded that Dr. Nass' care of Patient 2 evidenced a lack of ability or fitness to discharge the duties she owed him because "poor documentation in the progression of disease...[and] delay in advising inpatient or at least inperson assessment." Tr. 1/31 499:14-20. Related to **Count II & IV**, Dr. Courtney testified that Dr. Nass' treatment of Patient 2 evidenced a lack of knowledge or inability to apply principles of skills necessary to practice medicine. *Id.* at 500:4-6.

Patient 1 At-home Care

Dr. Nass' care of Patient 1 during the at-home phase of the patient's COVID illness demonstrated incompetence under **Counts I, II** and substantiated **Count IV** because Dr. Nass failed to adequately track the progression of the illness and Patient 1's relevant symptoms. Patient 1's medical records and Dr. Nass' testimony indicate that Dr. Nass did not track Patient 1's symptoms. *See* Staff Exs. 9 & 16. Dr. Nass relied on family members who told her Patient 1 "was doing okay, and so I took them at their word, because, again, this was a phone call or a text message." Tr. 10/11 64:15-17. Patient 1 testified that she was able to speak for herself. Tr. 7/28 1324:18-1325:1. Dr. Courtney identified the obvious flaws of Dr. Nass' approach: "she didn't speak with the patient herself. She's relying on secondhand knowledge of what's going on with the patient, so I—I can hardly suggest that—that that is an adequate assessment of her patient." Tr. 1/31 465:1-5.

Dr. Nass made the only notation of Patient 1's COVID symptoms the morning Patient 1 went to the hospital on December 19, 2021. This note reflects that the patient had previously experienced an extended period of abdominal pain "24/7" and a poor appetite for two weeks, and that the patient was weak and dizzy. Staff Ex. 9 pdf 50 p. 49. Despite the family having access to finger monitors, no pulse oxygenation levels were reported, and Dr. Nass never recorded pulse oxygenation levels in Patient 1's medical records. The only reference to pulse oxygenation levels appears in a text message from Patient 1's family member to Dr. Nass, which states simply "[o]xygen levels are ok (using the finger monitors)." Staff Ex. 16 pdf 107 p. 106. Even more troubling, Patient 1 testified that she did not know what oxygenation levels would be of concern. Tr. 7/28 1328:7-9. No other vital statistics or symptoms are recorded until the day of hospitalization, December 19th. Staff Ex. 9 pdf 50 p. 49. At the time of her admission, Patient 1's oxygen saturation was variable, and fell to 83% upon standing, which resulted in admission for "acute respiratory failure with hypoxia" that required treatment over a period of about a week. Staff Ex. 17 pdf 130 pp. 129; see also Tr. 7/28 1302:13-15 (hospital admission December 19th through the 25^{th}).

Dr. Courtney concluded, "the care given up to that point [Patient 1's hospitalization] did not clearly establish how well the patient was doing and whether or not they needed to go to the

emergency department prior to this date." Tr. 1/31 470:15-19. Dr. Courtney testified that Dr. Nass' treatment of Patient 1 demonstrated incompetence under the statutory standards in **Counts I, II & IV** because Dr. Nass failed to appropriately track and record relevant symptoms. *Id.* at 469:24-475:3. "There was not sufficient interaction with that patient to assess her quality of the illness and whether or not she needed more prompt in person assessment." *Id.* at 471:9-12. The inadequacies of Dr. Nass' monitoring and care of Patient 1 are self-evident. Even Dr. Nass' own clinical treatment expert, Dr. Marik, did not offer any testimony defending Dr. Nass' evaluation of Patient 1's symptoms or denying the need to track at-home COVID patients.

Patient 3 Single Telephone Call

Dr. Nass's care of Patient 3 violated **Counts I, II & IV** because Dr. Nass interacted with Patient 3 on only a single telephone call, during which Dr. Nass failed to adequately assess the patient or take an appropriate medical history. Dr. Nass' medical record for this patient is a single page, with one additional page of written prescriptions. Staff Ex. 28 pdf 281-282 pp. 1282-1283. Patient 3 testified she did not recall Dr. Nass taking her medical history, and none is recorded in the medical record. Tr. 7/28 1452:2-7 & Staff Ex. 28. Dr. Nass failed to conduct or record any physical exam or gather and record relevant vital statistics. Tr. 7/28 1449:13-19 & Staff Ex. 28. Dr. Courtney testified that a physical exam was necessary to assess whether the patient was in respiratory distress, tachycardic, dizzy or unsteady, having difficulty breathing, or had acceptable oxygen saturation. Tr. 1/31 506:20-507:3. Dr. Courtney testified that "even on a telephonic basis" a physician must conduct that examination. *Id.* at 507:7. Dr. Courtney concluded that Dr. Nass did not collect sufficient information to determine if Patient 3 required in-person assessment or not. *Id.* at 508:19-23. Dr. Courtney stated that Dr. Nass' failure to

adequately assess the severity of Patient 3's illness demonstrated a lack of fitness to discharge the duty owed to Patient 3 (**Counts I &IV**) and further evidenced a lack of knowledge or an inability to apply principles to carry out the practice of medicine (**Counts II & IV**). Tr. 1/31 512-513.

• Dr. Nass' failure to fully discuss risks, benefits, and options for treatment with Patients 1, 2, and 3 demonstrates incompetence (Counts I, II & IV).

Drs. Nass, Courtney, and Faust agreed that it is necessary to conduct a risk-benefit conversation with each patient regarding treatments and treatment alternatives. Dr. Courtney said "good one-on-one patient communication and a shared decision on the benefits and disadvantages of using such a medication" is required. Tr. 10/25 416:2-5. Dr. Nass testified related to a patient's "right" to choose a given medical treatment, that "[i]t's their right to have an opinion and it's their right to make a judgment once they've been educated on the risks and benefits." Tr. 10/25 384:22-24; *see also, id.* at 267:13-19. Dr. Faust agreed that risk and benefit had to be weighed and that the physician has "to discuss what treatments the existing treatments are. . . but if you're doing something in the place of evidence-based medicine, it's very important to inform the patient about that." Tr. 5/30 1127:11-18.

Dr. Courtney testified that monoclonal antibodies were an available outpatient treatment for outpatients at high risk of a severe COVID-19 infection during September and December 2021. Tr. 10/25 432:9-436:9; Tr. 1/31 486:4-12; & Staff Ex. 30-6. But the treatment should be given early "typically within the first week of illness." Tr. 10/25 436:7-9. Dr. Risch also testified monoclonal antibodies were appropriate COVID treatments once they became available. *See* Tr. 5/30 1166:8-11.

While the patients testified that they were "satisfied" with their conversations with Dr. Nass, none could list a single risk or benefit of the treatment that Dr. Nass had explained to them.

Similarly, Dr. Nass gave no specifics of any risk-benefit discussions she may have had with Patients 1, 2, or 3 regarding ivermectin or hydroxychloroquine. Patient 1 testified Dr. Nass boosted her confidence in the medication and that Patient 1 specifically relied on Dr. Nass as a board-certified physician, "who presumably, like every other physician, does their homework." Tr. 7/28 1313:13-15, see also, id. at 1317:21-1318:2 (expected Dr. Nass to tell her if there were better options). Patient 1 testified that Dr. Nass did not discuss other treatment options with her besides ivermectin and hydroxychloroquine. Id. at 1317:3-17. Patient 1 indicated that Dr. Nass did not discuss any specific risks or benefits of ivermectin as a treatment option. Id. at 1312:19-1313:3. Patient 2 similarly did not recall any discussions with Dr. Nass about risks of taking ivermectin or any other treatment options. Id. at 1371:22-1372:5. Demonstrating the essential importance of the Board's oversight of licensed physicians, Patient 3 testified that she relied on Dr. Nass' licensure as validation that her prescription for hydroxychloroquine was an appropriate treatment for COVID-19: "I guess, because she is the doctor . . . and because she is licensed that she would know that information." Id. at 1446:22-1447:1. Neither Dr. Nass nor any of the patients indicated that Dr. Nass explained that these medications did not meet the evidence-based standard of care for COVID-19.

Based on the testimony of the patients and the experts, it is clear that Dr. Nass failed to adequately discuss the risks and benefits of using the treatment options hydroxychloroquine or ivermectin with Patients 1, 2, and 3, and failed to adequately discuss other treatment options with Patients 1 and 2. In committing such failures, Dr. Nass demonstrated both a lack of ability or fitness to discharge the duty owed to patients (**Counts I & IV**) and a lack of knowledge or inability to apply principles in practicing medicine (**Counts II & IV**).

<u>Count IV</u>

The Board's Telemedicine Rules, Chapter 6, went into effect in December 2016. Dr. Nass erroneously argues that Executive Order 16 FY 19/20 (Licensee Ex. 17) suspended the telehealth rules. While that Order did suspend limited sections of Chapter 6 governing patient privacy and confidentiality, the Order did not suspend the vast majority of the rule, including not suspending the requirement that physicians meet the same standard of care as required for inperson treatment. And most importantly, the Executive Order Dr. Nass attempts to rely on to excuse her telemedicine practices was revoked before her care of Patients 1, 2, and 3 relevant to this case. Staff Rebuttal Ex. 129 (Executive Order 40 FY 20/21, revoking all aspects of Licensee Ex. 17 on or before August 30, 2021). Licensee Ex. 17 and any arguments about the suspension of Maine's telehealth rules are accordingly irrelevant to this proceeding.

Dr. Nass may also erroneously argue that Medicare or MaineCare guidelines regarding telehealth or the standard of care are somehow operative in this case. However, all the evidence indicates that the patients paid Dr. Nass in cash, without relying on MaineCare, Medicare, or any other insurance coverage or reimbursement. The Board should not give any weight to this clearly incorrect line of argument. The Board's statutes and rules set the standards that govern the standard of care and the practice of medicine by physicians in Maine. 32 M.R.S. § 3269; *see also* 10 M.R.S. § 8008.

The Board's governing law, 32 M.R.S. § 3282-A(2)(H), requires licensees to follow Board rules. Board rules Chapter 6 §§ 1(3), 1(4) and 3(3) require physicians practicing through telemedicine to meet the same standard of care as licensees providing traditional in-person health care. Staff Ex. 116 pdf 2495-2496 pp. 2721-2722. As cited above, Dr. Courtney concluded Dr. Nass failed to meet the standard of care for treating COVID patients when providing care for

Patients 1, 2, and 3. Although Dr. Nass' telemedicine expert, Dr. Kory, thought Dr. Nass' treatment rendered by telehealth was appropriate or met the standard of care, he admitted that he did not have Maine's standards in mind when he reached his conclusion. Tr. 7/28 1571:3-7. Dr. Marik, another of Dr. Nass' experts, testified that Dr. Nass exceeded the standard of care, but gave only the fact that Dr. Nass was available by cellphone and text as the rationale for this opinion. *Id.* at 1503:11-20.

Where Dr. Nass' care of Patients 1, 2, and 3 failed to meet the standard of care, that care simultaneously failed to conform to the appropriate standards of care while using telemedicine as alleged in **Count IV**.

• <u>Count V</u>

The Board's telehealth rule Chapter 6 § 3(7) requires physicians to conduct appropriate medical interviews and examinations of patients when treating or prescribing via telehealth. A physician may conduct this interview and examination by telemedicine only

if the technology utilized in a telemedicine encounter is sufficient to establish an informed diagnosis as though the medical interview and physician examination had been performed in-person. Prior to providing treatment, including issuing prescriptions, electronically or otherwise, a licensee who uses telemedicine in providing health care shall interview the patient to collect the relevant medical history and perform a physical examination, when medically necessary, sufficient for the diagnosis and treatment of the patient.

Staff Ex. 116 pdf 2497-2498 pp. 2723-2743. As described in detail above, in providing care Dr.

Nass failed to request, receive, or track relevant physical symptoms of Patients 1 and 2

throughout the at-home portion of their illnesses, conducted limited medical history reviews for

Patients 1 and 2, and failed to collect any medical history or conduct an appropriate examination

of Patient 3.

Dr. Marik testified physical examination was not possible during a telehealth visit. Tr. 7/28 1484:10-16. That does not mean the patient's physical state or symptoms should not be evaluated. As described above, Dr. Courtney testified about essential COVID symptoms that Dr. Nass could and should have inquired about, evaluated, and recorded while she was providing multi-day telehealth-only care to Patients 1 and 2 at home, and while she was determining Patient 3's safety to remain at home. By failing to conduct medical interviews and relevant examinations required to sufficiently make informed treatment decisions, despite being able to do so, Dr. Nass violated this Board rule.

• <u>Count VI</u>

Board rule Chapter 6 § 3(9) requires:

A licensee who uses telemedicine in providing health care shall ensure that the patient provides appropriate informed consent for the health care services provided, including consent for the use of telemedicine to examine, consult, diagnose and treat the patient, and that such informed consent is timely documented in the patient's medical record.

Staff Ex. 116 pdf 2498 p. 2724. Clearly, Dr. Nass failed to document in the patient records any purported informed consent for Patients 1, 2, and 3. Although the patients themselves testified that they gave "informed consent," their testimony discussed above shows that their consent was something less than "informed." At a minimum, they did not receive full information about the prescribed treatments or alternatives, which, according to the standards Drs. Nass, Courtney, and Faust all agreed on, prevented the patients from having sufficient information on which to base their consent.

<u>Count VIII</u>

Dr. Nass violated the clear mandate of Chapter 6 § 3(12)(B), which requires a physician providing care via telemedicine to "[r]efer a patient to an acute care facility or an emergency

department when referral is necessary for the safety of the patient or in the case of an emergency." Staff Ex. 116 pdf 2499 p. 2725. As detailed above, Dr. Courtney testified unequivocally that Patient 2's status required immediate referral to acute or emergency care as soon as Dr. Nass was informed of it mid-afternoon on December 15th and again that evening. Dr. Nass, however, disregarded the suffering of Patient 2. Patient 2 was left at home to fend for himself with the well-known and most dangerous COVID-related cause of death: hypoxic respiratory failure. He was left at home in critical and deteriorating condition, hypoxic, tachycardic, having difficulty breathing, and in an impaired mental state. Dr. Nass was not giving this patient what he wanted, she was failing to give him the minimum care he was owed. Dr. Nass failed to immediately refer a high-risk COVID patient—who was at the edge of dying—to the emergency room.

• <u>Count IX</u>

Chapter 6 § 3(20) prohibits a licensee from prescribing to a patient based solely on a telephone evaluation in the absence of physician-patient relationship. Staff Ex. 116 pdf 2502 p. 2728. Subsection 3(20) also requires that "[t]elemedicine technologies, where prescribing may be contemplated, must implement measures to uphold patient safety in the absence of traditional physical examination." *Id.* at pdf 2503 p. 2729. Finally, physicians are allowed to prescribe within their discretion based solely via telemedicine patient encounters where the prescribing physician meets the mandatory requirement that they "ensure that the clinical evaluation, indication, appropriateness, and safety consideration for the resulting prescription are appropriately documented and meet the applicable standard of care." *Id.*

It is undisputed that Dr. Nass interacted with Patients 1, 2, and 3 solely by telephone or text, and that she prescribed to all of them. Dr. Nass talked with each patient only once before

prescribing for them. She took only a limited history of each, even though all three patients were high-risk and had comorbidities. Staff Exs. 9, 16, 21 & 28. As explained above, Dr. Nass had only a single phone call with Patient 3, during which Dr. Nass failed to perform any examination and did not take any medical history. Yet, she treated and prescribed for this patient anyway. This single, short, incomplete interaction with Patient 3 clearly violates the prohibitions in Chapter 6 § 3(20).

In addition, if the Board concludes that Dr. Nass's minimal interactions with Patients 1 and 2 (lack of medical histories and examinations) were insufficient to create a valid physicianpatient relationship, then Dr. Nass would have further violated this rule by providing healthcare via telemedicine outside a valid physician-patient relationship. For Patients 1 and 2, as detailed above, Dr. Nass clearly failed to meet the other requirements of Section 3(20), because she did not implement measures to uphold patient safety in the absence of traditional physical examination and did not document clinical evaluation, indication, appropriateness or safety considerations for the prescriptions, and again, most essential, she failed to meet the standard of care in prescribing for and treating these patients.

• The Board May Find Dr. Nass' Experts Unconvincing

Dr. Nass presented four expert witnesses: Drs. Risch, Marik, Kory, and Katsis. None of them are Maine-licensed doctors, none of them were familiar with the Board's specific laws and standards, none of them applied those standards to the facts in this case.

Dr. Risch's scientific opinion is reflected in the exhibits he provided, 151A, 151B, and 151C, two of which were roundly criticized by Dr. Faust on scientific grounds. The two apparently most pertinent to Dr. Nass' argument (151B and 151C) were prepared for this hearing and not validly published anywhere. Dr. Risch and Dr. Faust had very different views not just

about what constitutes valid science, but about the key issue in this case: whether Dr. Nass relied on valid science in making her patient care decisions. Dr. Risch first testified about Dr. Nass' prescribing to Patients 1, 2, and 3, "I'm saying that those prescriptions are an appropriate level of care because there was *no standard of care in the pandemic in the first place*." Tr. 5/30 1258:25-1259:3 (emphasis added). He then added, "I can't speak explicitly to what's referred to as the standard of care, but I can say that it seems appropriate to me." *Id.* at 1259:20-22. The Board would be justified in disregarding Dr. Risch's testimony as unconvincing.

Dr. Marik opined that Dr. Nass' mere text-message accessibility to patients meant she went above and beyond the standard of care. Dr. Marik is no longer a licensed physician in any jurisdiction. When Dr. Marik previously held a medical license, he was disciplined by the Virginia Board of Medicine for 18 instances of prescribing controlled substances outside the limits of his then-active medical license. *See* Staff Ex. 145. He admitted that conduct to the Virginia board, in writing, then denied that very same conduct to this Board during testimony. Tr. 7/28 1521-1522. Along with Dr. Kory, Dr. Marik had an article retracted from publication over concerns the data was inaccurate. Staff Ex.150. The Board would be justified in disregarding Dr. Marik's testimony as unconvincing and unreliable.

Dr. Kory admitted that his conclusions about Dr. Nass' comportment with the telemedicine standard of care were not based on Maine's telehealth standards. As mentioned above, a scientific journal article of Dr. Kory's was retracted following alleged inaccuracies in the data. (Staff Ex. 150). Considering Dr. Kory's lack of evaluation based on the relevant standards in this case, the Board would be justified in disregarding Dr. Kory's testimony as unconvincing.

Dr. Katsis' testimony primarily focused on irrelevant issues in Oklahoma. To the extent he provided any opinion relevant to this Maine case, it was consistent with other experts: off-label prescribing must be evaluated on the <u>merits</u> of the underlying medical decision-making, not on the basis of whether it is on- or off-label *per se*. Aside from this point of agreement with the other experts, the Board would be justified in ignoring Dr. Katsis' irrelevant testimony.

B. Medical Recordkeeping (Counts XI, XII & XIII)

• <u>Count XI</u>

Chapter 6 § 3(9) requires that informed consent (for both treatment and the telemedicine itself) be "timely documented in the patient's medical record." Staff Ex. 116 pdf 2498 p. 2724. Dr. Nass failed to document in the patient records any informed consent for Patients 1, 2, and 3. *See* Staff Exs. 9, 16, 21 & 28.

• <u>Count XII</u>

Chapter 6 § 3(13) requires licensees who use telemedicine "to ensure that complete, accurate and timely medical records are maintained for the patient when appropriate." Staff Ex. 116 pdf 2499 p. 2725. As discussed in detail above, Dr. Nass failed to record relevant symptoms, patient status, or disease progression information for Patients 1 and 2 and any vital signs or medical history for Patient 3. For these reasons, Dr. Courtney concluded the records were inadequate. In at least one patient record, Dr. Nass also failed to know and record information that she testified she always asks about: allergies. No allergies were documented by Dr. Nass for Patient 1, and Dr. Nass testified "Patient one had no allergies," which Dr. Nass said she knew "because I ask every patient and I write them down when they have allergies." Tr. 10/25 350:8-18. The hospital record contradicts Dr. Nass. Staff Ex. 17 pdf 124 p. 123 ("Allergy: Penicillin G; Reaction: Rash" (Patient 1's hospital record, first page)). On cross-examination, Dr. Courtney agreed that certain uncontested aspects of the patient records were adequate for limited windows of time or limited purposes, for example, the notes of Patient 1's symptoms on December 19th "were sufficient to understand the patient's condition" to refer her to Pen-Bay ER. Tr. 1/31 598:6-22 & 600:2-17. Despite the limited appropriateness of some patient record entries, Dr. Courtney consistently testified on direct and cross-examination that the records were inadequate overall.

The omissions throughout the patient records are obvious. A brief review of Staff Exhibits 9, 16, 21, and 28 will reveal that the records are inadequate to document even Dr. Nass' limited treatment of these patients.

<u>Count XIII</u>

Chapter 6 § 3(14) requires a licensee who uses telehealth to have written protocols to protect patient privacy and confidentiality, ensure proper patient identification, and provide for data retrieval. Staff Ex. 116 pdf 2499 p. 2725. Dr. Nass failed to institute these required protocols. As a result she was unable to retrieve patient-specific information when needed and to identify Patient 2 during a text message exchange. Staff Exs. 16 (email subject line: "Apologies I am just learning how to do this to provide the data you requested") & 21 pdf 238 p. 237 (Dr. Nass: "I cannot remember your name, town and date of birth"). These written protocols were required even before COVID began. And as discussed above, this section of Chapter 6 was in full force in the fall of 2021 when Dr. Nass treated these patients.

C. Truth-Telling and Misrepresentation (Count XIV)

The Board's governing law prohibits fraud, deceit, or misrepresentation in connection with services rendered within the scope of the license issued. 32 M.R.S. § 3282-A(2)(A). Under Maine law a misrepresentation can be as simple as a mere misstatement of fact. *Ogbonna v. Me*.

Bd of Pharmacy, AP-18-14, slip op. at 5-6 (Me. Super. Ct., Ken. Cnty., Dec. 13, 2018). There can be no question that Dr. Nass made such a misrepresentation. Dr. Nass admitted repeatedly, publicly, and directly to the Board that she "lied" to a pharmacist about a hydroxychloroquine prescription by falsely stating she prescribed it to treat Lyme disease. Tr. 10/11 30:20-24; *see also* Staff Exs. 18, 21, 127 & 128.

To justify her lie, Dr. Nass argues the pharmacist was prohibited from dispensing hydroxychloroquine by a Board of Pharmacy policy. Licensee Ex. 11. But the Pharmacy policy (even if it applied to Dr. Nass, which it does not) does <u>not</u> prohibit dispensing hydroxychloroquine for COVID. Instead, it encourages pharmacists to get a COVID diagnosis code, dispense only a two-week supply, and avoid dispensing for prophylactic-only use, all to ensure sufficient supply of the medication for other uses. Licensee Ex. 11. Dr. Nass did not have to lie. Even if the policy said what Dr. Nass claims, she had other options. She could have tried to speak to the pharmacist-in-charge, or she could have tried another pharmacy. Instead of taking those available and appropriate actions, Dr. Nass lied to the pharmacist who provided care to Patient 2.

D. Additional Alleged Violations (Counts XVIII & XIX)

Count XVIII alleges Dr. Nass failed to timely respond to a Board complaint notification. The relevant notification is admitted into evidence as Staff Ex. 97. The Board may consider Staff Exhibits 99-101 and 123, and relevant testimony to determine whether Dr. Nass timely responded. The statute requires the licensee to "timely respond to a complaint notification," without further detail. 32 M.R.S. § 3282-A(2)(R). The narrow question for the Board is whether Dr. Nass' request for more time (which was granted), followed by the Superior Court lawsuit about the subpoenas, and a written refusal to respond, constitute a timely response to a Board complaint under the statute.

Count XIX relates to subpoenas issued by the Board, which Dr. Nass challenged in Superior Court. Staff Ex. 123. On December 21, 2022, the Court dismissed the lawsuit regarding the subpoenas. The Court instructed that a proper challenge to the subpoenas is first directed to the Board under 5 M.R.S. § 9060(1)(C), at which time the Board can uphold, modify, or quash its own subpoena. Further, citing to § 9060(1)(D), the Court indicated that the Board could enforce its subpoenas through its own Superior Court action. Licensee then filed a Motion to Quash the Board's subpoenas on January 9, 2023. On September 12, 2023, the Hearing Officer issued an Order ruling that Licensee's motion to quash was untimely.

In light of the Superior Court's Decision and Order, we recommend the Board <u>not</u> find a violation of Count XIX.

Dated this 15th day of September, 2023.

<u>/s/ Jennifer Willis</u> Jennifer Willis, AAG Timothy Steigelman, AAG Lisa Wilson, AAG Office of the Attorney General 6 State House Station Augusta, ME 04333 jennifer.willis@maine.gov 207.626.8800

PATIENT 1	PATIENT 2	PATIENT 3
COUNTS I & IV	COUNTS I & IV	COUNTS I & IV
1. Prescribed ivermectin.	1. Prescribed ivermectin &	1. Prescribed
2. Failed to inquire about or	hydroxychloroquine.	hydroxychloroquine.
track relevant symptoms to	2. Failed to inquire about or	2. Failed to provide adequate
monitor COVID progression	track relevant symptoms to	risk-benefit info.
and be able to assess whether	monitor COVID progression.	3. Gathered no medical history,
referral to acute care was	3. Failed to provide adequate	no vital signs, conducted no
required.	risk-benefit info for treatment	examination prior to prescribing
3. Failed to provide adequate	offered and options.	and treating.
risk-benefit info for treatment	4. Failed to escalate care.	
offered and options.		
COUNTS II & IV	COUNTS II & IV)	COUNTS II & IV
Relied on inadequate science	1. Relied on inadequate	Relied on inadequate science to
to justify treatment of COVID	science to justify treatment of	justify treatment of COVID with
with ivermectin.	COVID with ivermectin &	hydroxychloroquine.
	hydroxychloroquine	
	2. Did not appreciate severity	
COUNTRY	or meaning of symptoms.	COUNTRY
COUNT V	COUNT V	COUNT V
Failed to track and monitor	Failed to track and monitor	Gathered no medical history, no
relevant symptoms throughout	relevant symptoms	vital signs, and conducted no
at-home care.	throughout at-home care.	examination prior to treating and prescribing.
COUNT VI. Failed to provide	COUNT VI. Failed to	COUNT VI . Failed to provide
adequate risk-benefit info for	provide adequate risk-benefit	adequate risk-benefit info for
treatment offered and options,	info for treatment offered and	treatment offered, therefore
therefore patient could not	options, therefore patient	patient could not provide
provide informed consent.	could not provide informed	informed consent.
	consent.	
	COUNT VIII.	
	1. When hypoxia &	
	tachycardia reported	
	afternoon of Dec. 15th, failed	
	to refer to acute care. 2.	
	When hypoxia reported again at $7/20$ m on $12/15$ failed	
	at 7:30 p.m. on 12/15, failed	
COUNT IX. Prescribed for	again to refer to acute care. COUNT IX. Prescribed for	COUNT IX. Prescribed for
patient based solely on a	patient based solely on a	patient based solely on a phone
telephone interaction, failed to	telephone interaction, failed	interaction without medical
uphold patient safety, and	to uphold patient safety, and	history or adequate exam, failed
failed to meet standard of care.	failed to meet standard of	to uphold patient safety, and
Tanted to meet standard of eare.	care.	failed to meet standard of care.
l	- Cur C.	funda to most standard of care.